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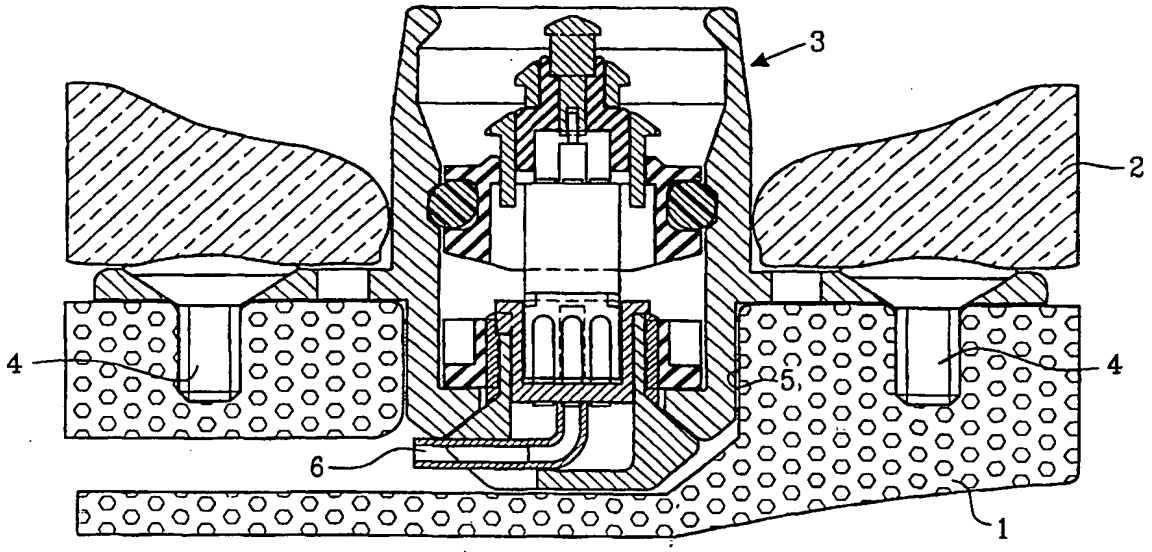


(57) Abstract

The present invention relates to a percutaneous bone anchored transferring device for obtaining a transfer of an electrical signal and/or energy and/or distribution of a drug and/or airing of a body cavity, whereby the device comprises a transferring device (3), a connection unit (21), connected to the inner of a body, a middle insert (31) having connection units (24, 26) and an outer contact unit (41).

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**TITLE**

**PERCUTANEOUS BONE ANCHORED TRANSFERRING DEVICE**

**DESCRIPTION**

Technical field

There is a great need for transferring electrical information and/or electric energy to an inner subcutaneous permanently implanted unit at several medical-technical applications.

The present invention relates to a percutaneous bone anchored transferring device, preferably by means of which an outer electrical unit can be connected to an inner implanted subcutaneous unit.

Varieties of such connecting devices are not unknown, but the present invention differs, i.a. in that the bone anchored and skin penetrating transferring device can be connected in a simple way, beneath the outer limiting surface of the bone, to and from the implanted set of cables/joining device, which transfers electrical information and/or energy, drug, etc., to the inner implanted unit. Furthermore, the new transferring device is designed in such a way that the dimensions are small and that the biocompatibility properties become good.

The primary application described in the description is an electrical connection device which is designed for daily use, i.a., in that the connection becomes simple and in such a way that substantially free rotational positioning is allowed, and that the connection is easily maintained and that details being worn out simply can be exchanged. The connection is furthermore designed in such a way that it disconnects due to an outer mechanical influence being large enough.

Background of the invention and prior art

In spite of an increasing need for a percutaneous connecting device for permanent use, in particular for the transfer of electrical information and/or electric energy there is no commercially available unit being allowed for clinical use (as far as the inventor is aware of in December 1997). This, in spite of the fact that there are several patents within the field.

As a conclusion, it can be said that the reason that these patents have so far not lead to any commercial product is probably due to the fact that the patents describe connecting devices which are either too complicated in that they contains too many poles and ingoing components or that they do not attend to all the nuanced demands raised from a biocompatibility, anatomical, surgical, electric, patient safety and handling points of view on a permanent, percutaneous, electric connecting device for daily use . In the following some relevant published patents concerning electrical connecting devices are commented in particular with regard to differences to the present invention as described.

In US-A-5,562,670 to Brånemark an electrical connecting device is described which is applied by means of a threaded tubular implant where its inwardly turned end has a central bore. Contact means and set of cables are introduced and fixed from the outside of the implant. This is a patent by the pioneer and the inventor to the world comprising industrial business of titan implants of today concerning dental rehabilitation, bone anchored hearing aids, and face prosthesis, knee and finger joints etc, professor P-I Brånemark. Without his basic research activities around biomaterial research in general, and titan implants in particular a long row of new applications/inventions had not seen the light. When it comes to practical realization of the electric connecting device described in US-A-5,562,670 there is a weakness in that the implanted set of cables and the inner implanted unit have to be so small that it can pass through the central bore of the implant. In most applications, however, the inner implant is to large to be able to pass in through the central bore of the implant. In these cases the units have be surgically implanted as an integrated unit or become mounted together with the implant in place or become connected by means of a further implanted and connecting device being small enough. If the contact means should be repaired or maintained, which is necessary with regard to the environment as a skin related implant is subject to (contact surfaces become oxidized etc.), this has to be done in the tube in the patient. If one should wish to remove/exchange the connecting device the whole implanted set of cables has to be removed. Fixation of the implant using threads means that the bone anchored part of the implant has to have a diameter large enough to encompass even the thread as such which clearly restricts the possibilities to encompass connecting details therein, as well. It is desired to encompass the connecting details in the bone anchored part

of the transferring device to reduce the total height of the transferring device. A well functioning transferring device should not extend outside the skin level more than 1 to 3 mm in order to avoid damages from optional outer mechanical violence and in order that the implant should be experienced as acceptable from an aesthetical point of view. Furthermore, a screw implant has to be rotated at the application which means that an asymmetrical design of the implant is very hard to realize. An asymmetric design of the implant is a desire as the bone thickness where the implant, from a practical point of view has be placed, is so thin that the set of cables, as a rule, has to leave the implant in a radial direction. Furthermore, the inner implanted unit has to rotate together at the application if it has been premounted and passes through the transferring device (due to the fact that it is to large to be applied afterwards through the bore), which will lead to practical problems, as well.

US-A-3,870,832 to Fredricson discloses a connecting device for the application of a microphone, which device corresponds, in principle, with the Brånemark patent. Fredricson shows that the retention of the microphone element is done using a locking nut which is applied using an outwardly turned thread on the implant, which should lead to a potential risk for bacterial accumulation and risk for skin irritation. Besides, the construction according to this patent, is characterized by the same weaknesses as described above with reference to patent 5,562,670.

US-A-5,604,976 to Stobie et al discloses a connecting device for a great number of conductors, the inner connecting device of which is not intended to be lowered beneath the surface of the outer limiting surface of the bone, but become fixed above the same but below the soft tissue. In this connecting device the set of cables is lead to the inner implanted unit on the top of the bone beneath the soft tissue. Problems reported in clinical tests using such an arrangement shows that the set of cables having a realistic dimension (minimum 1 to 2 mm in diameter) and being a little elastic creates biocompatibility problem at the skin penetration, probably due to the occurrence of small movements between skin and bone with a foreign material there between. Furthermore, the necessary skin reduction can be jeopardized if the set of cables has not got a very small diameter. The connection can be severed apart by means of tools to loosen a screw connection and can not, for any reason,

be disconnected in daily use. This connecting technique further means that rotation of the outer connecting part is not possible and that an overloading protection from outer influence is missing.

US-A-5,507,303 to Kuzma discloses a connecting device where the implant, for sure, is anchored to the scull bone but where the skin/bone connecting tissue closest to the implant is separated from the scull bone using a large flange. A long experience from skin penetrating titan implants in the scull bone shows that it is of utmost importance that the skin around the penetration area has passed an adequate skin reduction and that the thickness reduced skin is allowed to grow against bone connecting tissue and scull bone (Tjellström, Anders, et al, The Bone Anchored Hearing Aid - design principles, indications and long-term clinical results, Otolaryngologic Clinics of North America, vol 28(1), 1995, pp 53-72). The flange of the actual connecting device hinders the skin to grow to the bone/bone connecting tissue, and the frequency of skin complications can be expected to be relatively high. Furthermore, the whole connecting device is placed outside both bone and skin, which means that its extending part above the skin surface becomes considerable. The retention between the connecting parts is done using magnetic force.

US-A-4,025,964 to Owens discloses a connecting device which unlike the connecting devices above is not anchored to the bone in a stable way. Even small movements of the implant relative to the skin will lead to a great risk for skin irritation. Fixation between the male and female parts of the connecting device is carried out using magnetic attraction force and the parts can not be rotated relative to each other.

US-A-3,995,644 to Parsons discloses a connecting device, as well, which is merely fixed to the skin, and intended to transfer an electrical signal, preferably for electrical stimulation of muscle units. Due to the fact that even small movements between skin and implant create irritation, this type of connecting devices should only be used temporarily and time restricted use.

Finally, there are a number of connecting devices which are intended to be used totally

subcutaneously, such as US-A-4,495,917 to Byers, but these are so different to the present invention concerning functional requirements and constructive solutions that a further analysis does not seem to be meaningful.

US-A-4,328,813 relates to a system for anchoring a brain cable and is only intended to geometrically fix or lock a cable such as an electrode for the stimulation of a certain point in the brain. The cable is thereby intended to be brought underneath the scalp to an electric stimulator. As the implant is manufactured in an elastic material, and provided with slots, the implant can not be used for a bone anchored percutaneous transferring device.

SE-C-503,790 relates to a passive screw implant for the transfer of vibrations from an outer vibrator (loud speaker) to the scull bone. Such an implant can not transfer electrical signals, energy or drugs to the inner of a body and, has not, when construed, been faced with the problems that the present invention provides a solution to.

The object of the present invention and features of a principle nature.

As mentioned above there is a great demand for, within several medical-technical applications, to transfer electrical information and/or electric energy or to communicate in an other way (e.g. to distribute drugs or to obtain airing of interior cavities and cell systems) from an outer unit to a subcutaneously implanted inner unit. Such subcutaneously implanted units can be hearing technical aids, e.g. coclear implants, middle ear implants, bone transfer implants, device for suppression of tinnitus and other medical-technical aids, e.g. stimulators of different types, registration means for biological signals, pumps for distribution of drugs, evacuation of liquids etc. In principle such devices consist of the following essential parts: outer unit, connecting device, skin penetrating and bone anchored transferring device, set of cables/communication channel, and subcutaneously implanted inner unit. A fundamental device utilizing a connecting device according to the present invention is provided in Figure 13, where the outer unit can e.g. be a hearing apparatus without loud speaker, and the inner unit can be a vibrator for the generation of bone transferred sound. The reason that a set of cables/communication channel between the transferring device and the inner unit is needed is that the bone thickness where the

transferring device from a practical and anatomical point of view has to be placed, is so thin that the inner unit will get no room. On the other hand there is plenty of room a short distance away, and closer to the auditory canal in the part of the temporal bone mentioned processus mastoideus. Where and how the inner unit will be placed is thereby dependent upon the application.

Although, if the present invention concerning a transferring device can be used for other communication of long term stable type, the following describes the primary application where an outer unit can be connected electrically to an inner implanted subcutaneous unit by means of the presently proposed transferring device. Varieties of such connecting devices are not unknown but the present invention is unique for the following reasons:

1. The application/fixation between the bone anchored part and the skin penetrating transferring device and the set of cables takes place below the outer bone level, preferably in the bottom part of the transferring device.

The advantages using this solution is

a. that the set of cables and the implanted inner unit can be assembled, and disassembled, respectively, separately, which is not only essential for facilitating the first installation but in particular at future events, of the type skin irritation/damages/maintenance/updatings, when the bone anchored and skin penetrating transferring device, and the set of cables (optionally including the inner unit), respectively, need to be exchanged, most often independent from each other. Further the transferring device can be removed in such a way that intact skin can be replaced without influencing the set of cables and an inner, implanted unit. In this way all inner vital parts can be retained resting underneath the skin, simultaneously as the skin above the penetration area is replaced for a longer or shorter term period. This way of acting can be of great importance, if the patient should like to temporarily cease the treatment but have the possibility to easily retain the treatment when the need, optionally, reoccurs;

b. that the transferring device and the set of cables (including the inner units connected to the other end thereof) can be rotated independently from each other at the mounting, and

optional dismounting, respectively.

C. that the skin closest to the penetration area can be reduced to the thickness desired, and be allowed to rest/heal to bone tissue and bone connective tissue which facilitates by the fact that the set of cables is drawn beneath and not over the outer bone surface.

2. The transferring device which is lowered into the bone tissue will be anchored by means of radial arms placed outside the outer surface of the bone, and will in turn be fixedly screwed to the bone tissue.

The advantages using this solution are:
that a first contact unit can be placed within the bone anchoring part of the transferring device (beneath the outer bone surface) without its outer diameter becoming undesirably large. This is possible as the bone anchoring part of the transferring device does not contains threads which otherwise take large room. By placing part of the connecting device into the bone anchoring part of the transferring device the part of the transferring device extending outside the skin can become minimal, which is advantageous partly from an aesthetical point of view, partly with regard to the risk for outer mechanical damage of the implant;

3. The connecting device comprises one middle connecting unit placed in the outer part of the transferring device. Hereby two connecting devices occur one outer to be connected to an outer unit, and one inner to be connected to the set of cables.

This solution provides the following advantages:

a. the middle connecting unit which will be exposed to the outer environment is a disposable detail designed to be simple to exchange if there should be bad contact due to the appearance of an oxide layer etc, or if a damage should occur in another way;

b. the middle connecting unit, in combination with a tightening ring, protects the inner and more sensitive connecting device from an outer environmental influence. Furthermore, the

middle connecting unit will serve, in combination with the tightening ring, as a first biological bar against the passage of undesired compounds/bacteria to the tissue inside the transferring device. The main bar in connection herewith, is, however, the screw joint between the connecting means of the transferring device and the set of cables;

c. the outer connecting device can be designed in such a way that it will allow free rotational positioning, will provide for a simple connection/disconnection, and will serve as an overload protection aid.

Experiences from more than 20 years of developing work with bone anchored hearing aids (Håkansson, Bo et al, The Bone Anchored Hearing Aid, Edited by Dan Tolman & P-I Brånemark, to be published) where more than 5000 patients have been operated and been provided with a mechanical bayonet joint (SE-C-8107161-5) show that al aspects mentioned above are of importance to have a connecting device work in clinical use for long time. It might seem that there is a restriction in that the present invention can hardly be realized using more than 4 to 6 poles, maintaining reasonable dimensions. If a larger number of poles is desired, as for example using the coclear implant, wherein up to 20 to 30 electrodes shall become separately provided it is suitable to utilize so called multiplexing. Multiplexing means that the information is transferred sequentially in a signal cable through the percutaneous electrical connection in order to then in an electronic way, become split up in the inner implanted unit and become distributed to the number of electrodes desired. Multiplexing is a well known technique when it is used within all communication (telecommunication and television) where one normally has not admittance to parallel cables. That which further speaks against a great number of poles in percutaneous electrical contact is that complexity and restrictions of both medical and technical character increases dramatically using an increasing number of poles. Generally, in most applications one can manage using three poles which then might be plus, and minus poles, respectively, as well as one signal cable. In specific hearing applications one sometimes wish to drive a push-pull vibrator where two cables are signal lines and one line is voltage feeding.

Short description of the figures

Figure 1 is a compilating cross sectional view of a helping aid where an electrical connecting device of the present invention is utilized.

Figure 2 is a cross sectional view of the present invention comprising a skin penetrating and bone anchored transferring device with its set of cables joined in the bottom part of the transferring device as well as a middle connection unit and tightening ring as mounted. In this embodiment of the middle connecting unit contact metal sheets of the outer contacting means attacks the unit with a radial force.

Figure 3 shows a cross sectional view of the transferring device shown in Figure 2.

Figure 4 shows the embodiment of Figure 3 seen from above.

Figure 5 shows the transferring device according to Fig. 2 to 4 using a connecting means for connection to an inner unit.

Figure 6 shows different details of a middle unit for insertion in the transferring device according to Fig. 2 to 4.

Figure 7 shows an embodiment of how the outer unit is connected to the middle connecting unit.

Figure 8 shows a simple tool for mounting, and dismounting, respectively, the middle connecting unit as well as how contact surfaces can be cleansed/maintained.

Figure 9 shows an alternative embodiment of the middle connecting unit, where the middle connecting unit is fixed by means of slotted radially spring biassed arms.

Figure 10 shows a lid used when the middle connecting unit and its contact surfaces should be protected, for example while taking a bath in salt water, and having a sauna.

Figure 11 shows an embodying example how the invention can be used at the distribution of a drug and evacuation/airing, alternatively, of internal cavities.

Figure 12 shows an alternative design of the contact means where the contact metal sheets of the outer contact means are connected using an axial contact force.

Figure 13 shows a schematic picture of a medical-technical helping aid where a connecting device according to the present invention is brought into place.

Description of the present invention

1 denotes a scull bone with its skin and skin tissue 2, which has been thinned using known surgical technology. An electrical connection 3 manufactured in a tissue compatible material

such as titan, is anchored into the scull bone 1 using screws 4, suitable of the same type of material, attached in said bone, whereby the connecting device is placed in the bone itself by means of a boring and lowering into the drilled hole 5. From the bottom part of the connecting device 3 a set of cables 6 has been drawn to an inner unit, not shown, such as a vibrator acting against the hearing bones.

The connection 3 comprises according to Fig. 2 - 4 a transferring part 11 which comprises a number of arms 12 provided with holes 13 for carrying a screw for anchoring it by means of screws 4. The number of arms can be three, four, five or more depending on the size and intended placing. The arms 12 are pivotable and inclinable to admit maximum of adaptation to the substrate to which they shall be screwed. The transferring part 11 has outwardly a substantially cylindrical form with the exception of the arms 12 as well as an inwardly substantially cylindrical form. In the upper part 14 the transferring part 11 is thinned to allow deformation if a large load should occur on the transferring part 11. On its inside the transferring part 11 of this embodiment has a groove 15 for receiving an O-ring 16. In the bottom part 17 of the transferring part 11 a hole 18 is arranged whereby its outwardly turned limiting surfaces 19 are obliquely arranged. The transferring part 11 is suitably teased in its lower Cylindrical part, the bottom part 17, to allow adaption to the tissue 1 in which it will be introduced. The transferring part 11 is shown as an integrated unit, but can be split and joinable by means of a screw joint over the plane in which the arms 12 are arranged.

In the transferring part 11 of this embodiment a connection means 21 is introduced from beneath and fixedly arranged tom the transferring part 11 by means of a screw joint by means of a locking nut 22. The connection means 21 shows a conical upper limiting surface 23 intended to abut perfectly to the hole 18 and its limiting surfaces 19 of the transferring part 11. In the connection means 21 an electrical connecting unit 24 is arranged the set of cables 6 of which is drawn out through a side opening 25 of the connection means 21.

To the connection means 24 a second connection unit 26 is arranged whereby one unit has male pins or metal sheets nd the other unit shows female pins or metal sheets for obtaining a good electrical connection between the connection units 24 and 26.

The connection unit 26 is in turn introduced into a middle insert 31 around which tree different poles 32 , 33, 34 are arranged and connected via metal sheets and cables to the connection unit 26, which is a unit built by cylindrical parts made of plastic or another non-conducting material. In the centre of the middle insert 31 a contact metal sheet of a plus pole 32 is placed. From this plus pole 32 a connecting line leads to a corresponding plus pole 26p on the connection unit 26. Around upper cylindrical part of the middle insert a contact metal sheet of a signal pole 33 is placed, which , via a not shown through hole, is connected to a corresponding signal pole 26s of the connection unit 26. Further, there is a contact metal sheet of a minus pole 34 arranged around the lower cylindrical part of the middle insert 31, whereby this minus pole 34 is in contact with a corresponding minus pole 26m of the connection unit 26, not shown.

An outer contact 41 is connected to the middle insert 31 with its different contact metal sheets, which contact can be a microphone unit of a hearing aid, another signal treatment unit, or as evident from Fig. 11 be a unit for the distribution of drugs or airing of a cavity. The outer contact 41 comprises a number of pins 42, 43, and 44 which connect to their respective contact metal sheet 32, 33, and 34. The pins 42 abut to the centre contact metal sheet 32 whereby this, at its point, is bent outwardly from the centre to rest against the sheet 32. In the same way the point of the sheet 43 bent outwardly to connect to the sheet 33. The pins 44 are bent inwardly towards the centre to connect to the edge of the contact sheet 34, which edge can be made stepped to allow stepping/variation of the position of the contact house/hearing apparatus from a rotational point of view. Hereby the sheet 34 is bent in an upward direction on two facing points to allow the pins 44 to be brought down beneath the edge of the contact sheet.

The pins 44 have a primary task to retain the outer contact 41 to the middle insert 31. At a load being high enough the pins will, however, pass over the edge to create a security release of the outer contact part visavi the inner middle insert and thereby the whole transferring device.

51 denotes a tool for removal and introduction of the middle insert comprising the

connection units from the transferring device 11. The tool 51 is hereby tubular and slotted in such a way that it by means of the grip 52 can be pressed together to retain a middle insert 31.

In fig. 10 a lid 61 is shown, which can be placed over the middle insert 31 when the outer contact 41 has been removed. It is suitable to apply the lid 61 when visiting a sauna or being in salt water. Hereby the lid 61 contains an upset 62 which snaps down over the upper edge of the transferring device 11.

In fig. 9 an alternative fixation of the middle insert 31 is shown, whereby its upper part is slotted and stretches outwardly, whereby this upper part stretches in beneath the edge of the upper part of the transferring device 11, the upper edge of which is hereby upset. Further, the embodiment shows an alternative arrangement of the O-ring.

In fig. 12 an alternative design of the contact means is shown having an axially elastic contact pin 71 which abuts a circuit card 72 provided with circuit lines.

Fig. 11 shows, as mentioned, an embodiment for the distribution of drugs in the form of a solution whereby an injection needle 81 penetrates a membrane 82 arranged in the middle insert as well as a membrane 83 arranged in the connection means. A tube 84 connects to the injection needle 81 for the addition of a drug solution, as well as a tube from the lower part of the connection means for the distribution at a suitable site in the body. These tubes and the injection needle can be used for the airing of a cavity, as well, such as a middle ear suffering from continuous inflammations.

## CLAIMS

1. Connection means for set of cables for transferring electrical information/energy to and/or from an implanted unit or for the administration of a drug or evacuation or airing of internal cavities, which connection means is intended to be connected to a transferring device arranged to a body bone,
**characterized** in
that the connection means (21) which is releasably arranged to said transferring device comprises a substantially cylindrical unit having tightening surfaces (19) in relation to said transferring device, and a connecting surface for the connection of a fixing means for the fixation to said transferring device (11).

2. Connection means according to claim 1, **characterized** in
that it comprises a through opening provided with a membrane (83).

3. Transferring device for communication to/fro an implanted unit or for the administration of a drug, comprising a body part being introducable into a bone, and a part being present above the bone surface, and comprising a substantially cylindrical body (11),
**characterized** in
that the part (11) of the transferring device situated above the bone surface contains a number of radial arms (12) arranged to be fastened to the bone (1) into which the device will be introduced.

4. Transferring device according to claim 3, **characterized** in
that the radial arms (12) are bendable and turnable fo adaptation to the substrate.

5. Transferring device according to claim 3, **characterized** in
that the cylindrical body (11) has such surface property that it is an integral unit towards to tissue after operation therein.

6. Transferring device according to claim 3, **characterized** in
that the body part (17) being lowered into the bone tissue and the body part (14) situated

above the bone surface consist of two individual parts which are connected to each other by means of a releasable joint.

7. Transferring device according to claim 3, **characterized** in that the upper part (14) of the body (11) is provided with a weakened zone.

8. Transferring device according to claim 1-2, **characterized** in that it shows a through going hole (18) in its bottom part (17) having tightening connection surfaces (19) to the connection means of claim 1.

9. Middle connection means for introduction into a transferring device according to claims 3-8, **characterized** in that it comprises an outer contact unit (41) and an inner middle insert (31) whereby the contact unit (41) is releasably arranged in said middle insert.

10. Middle connection means according to claim 9, **characterized** in that said middle insert comprises a number of contact metal sheet for obtaining an electrical transfer.

11. Middle connection means according to claim 9, **characterized** in that the middle insert (31) comprises a through opening provided with a membrane (82).

12. Middle connection means according to claim 9, **characterized** in that the outer contact unit (41) and the middle insert (31) are arranged to be released from each other at a predetermined load on the outer contact unit (41).

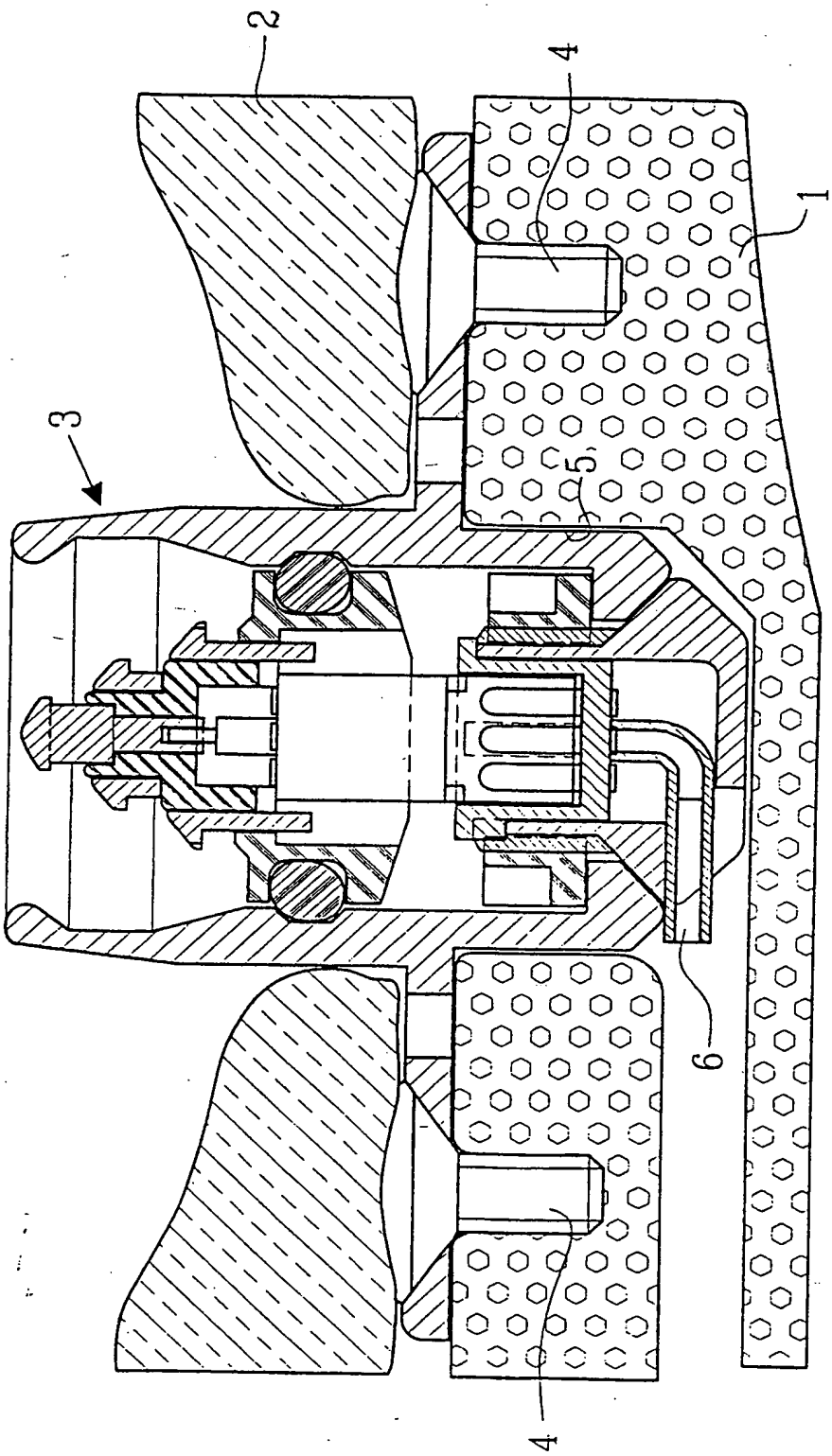


FIG.1

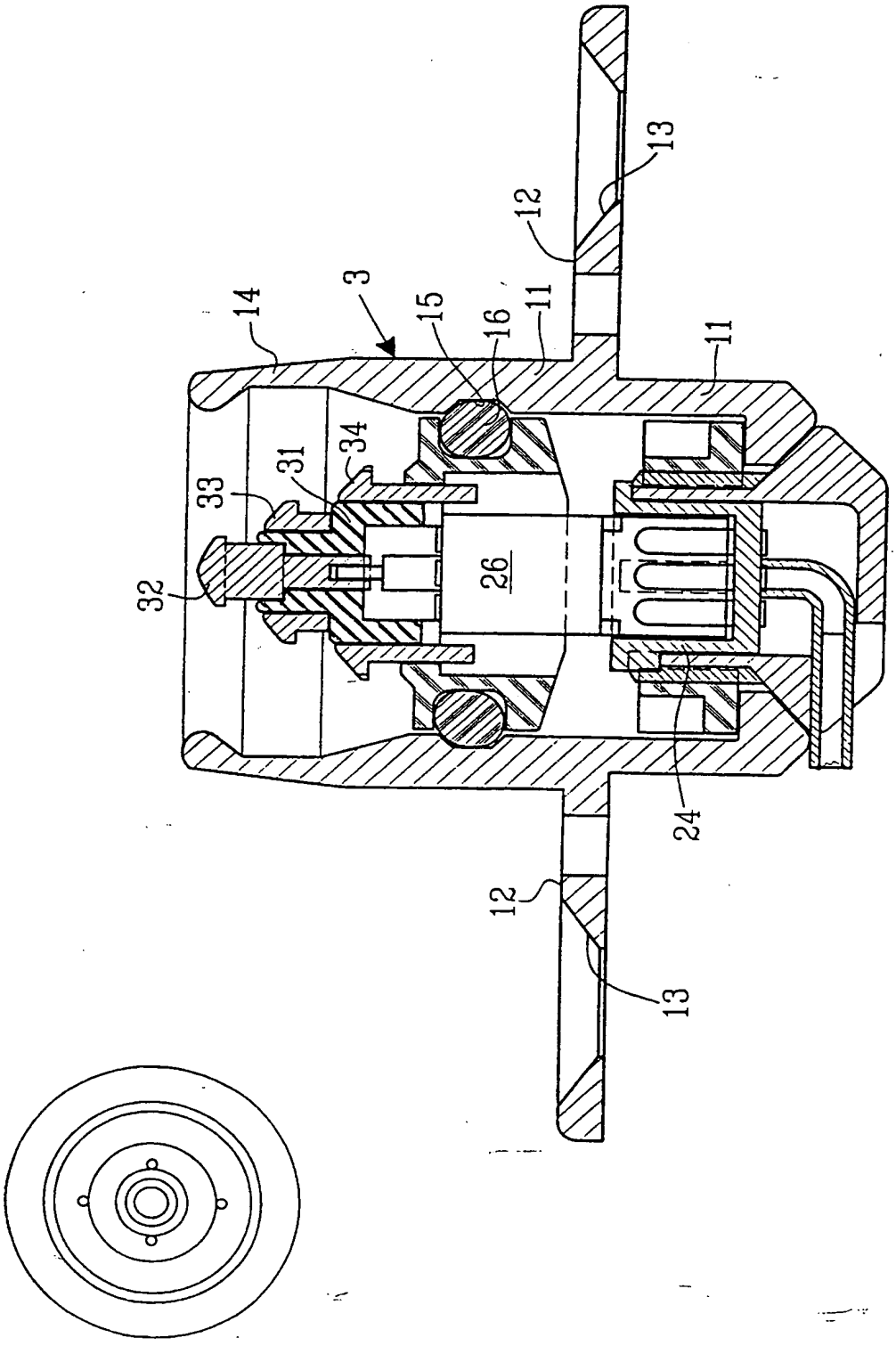


FIG.2

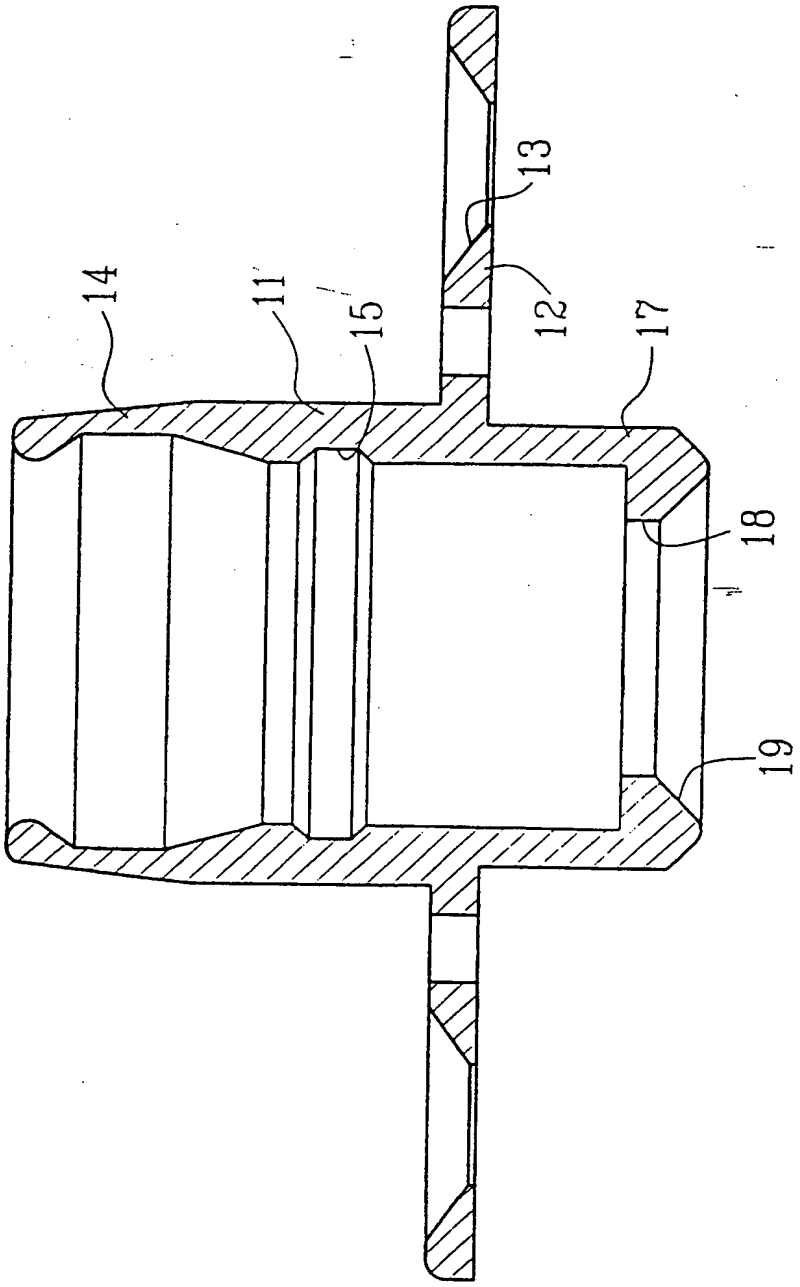


FIG.3

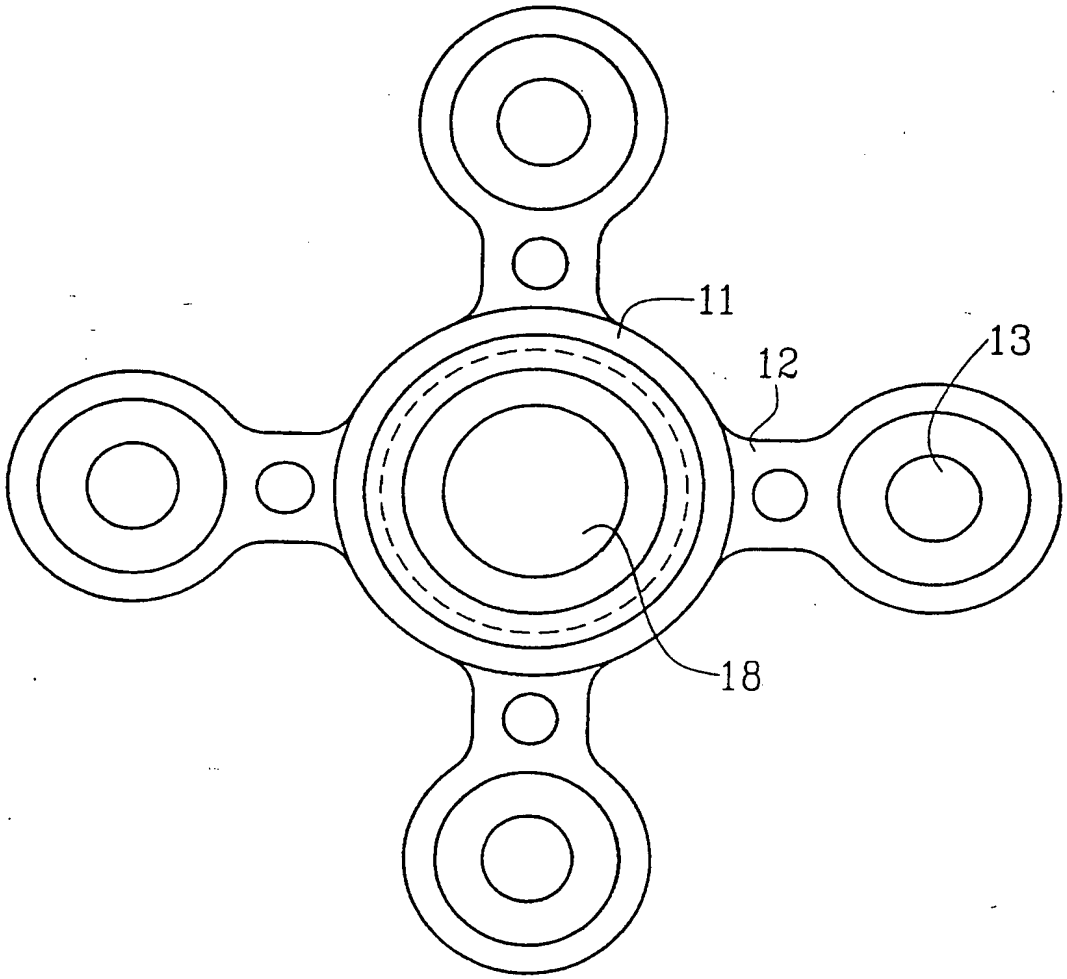


FIG.4

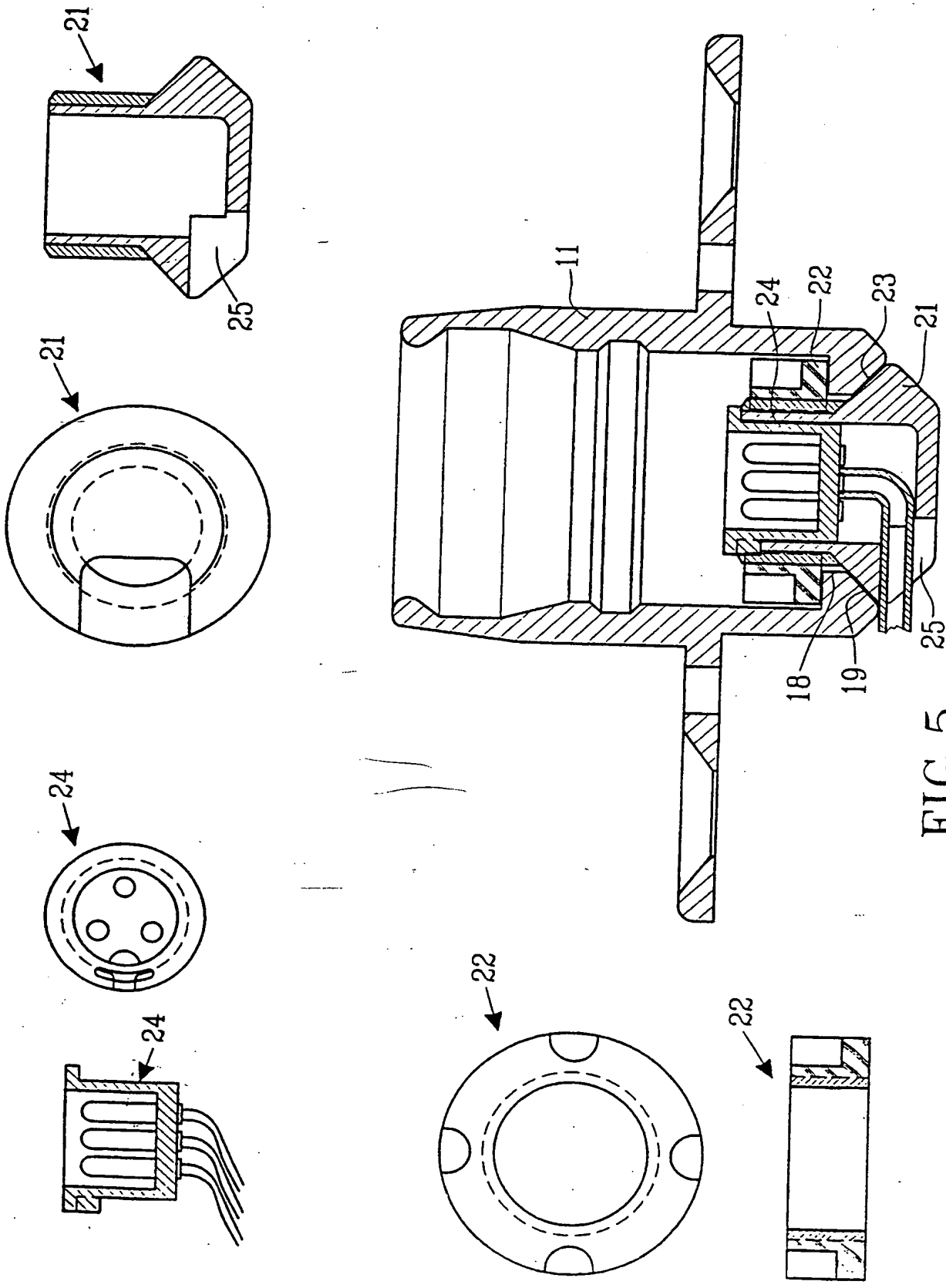


FIG.5

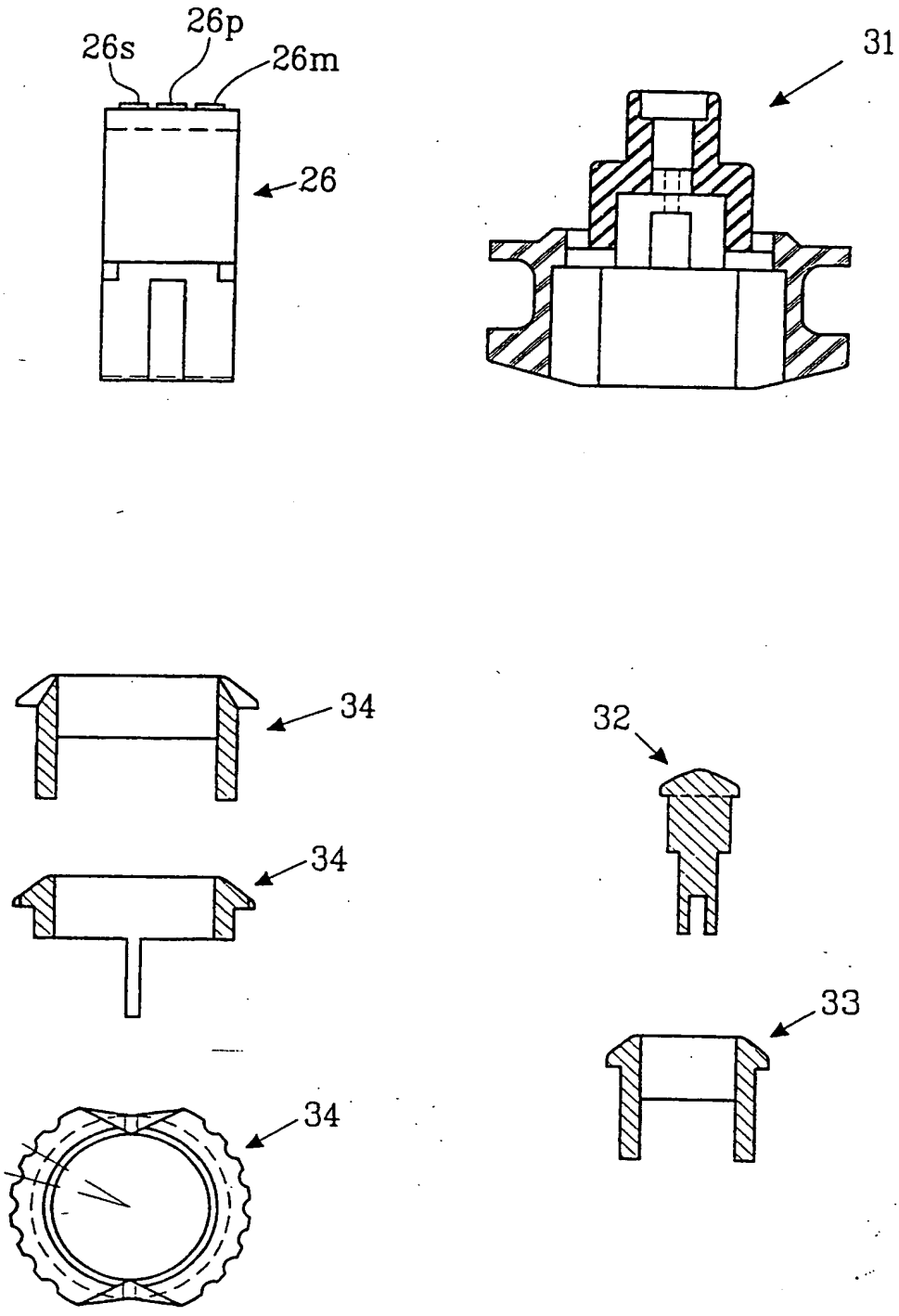


FIG.6

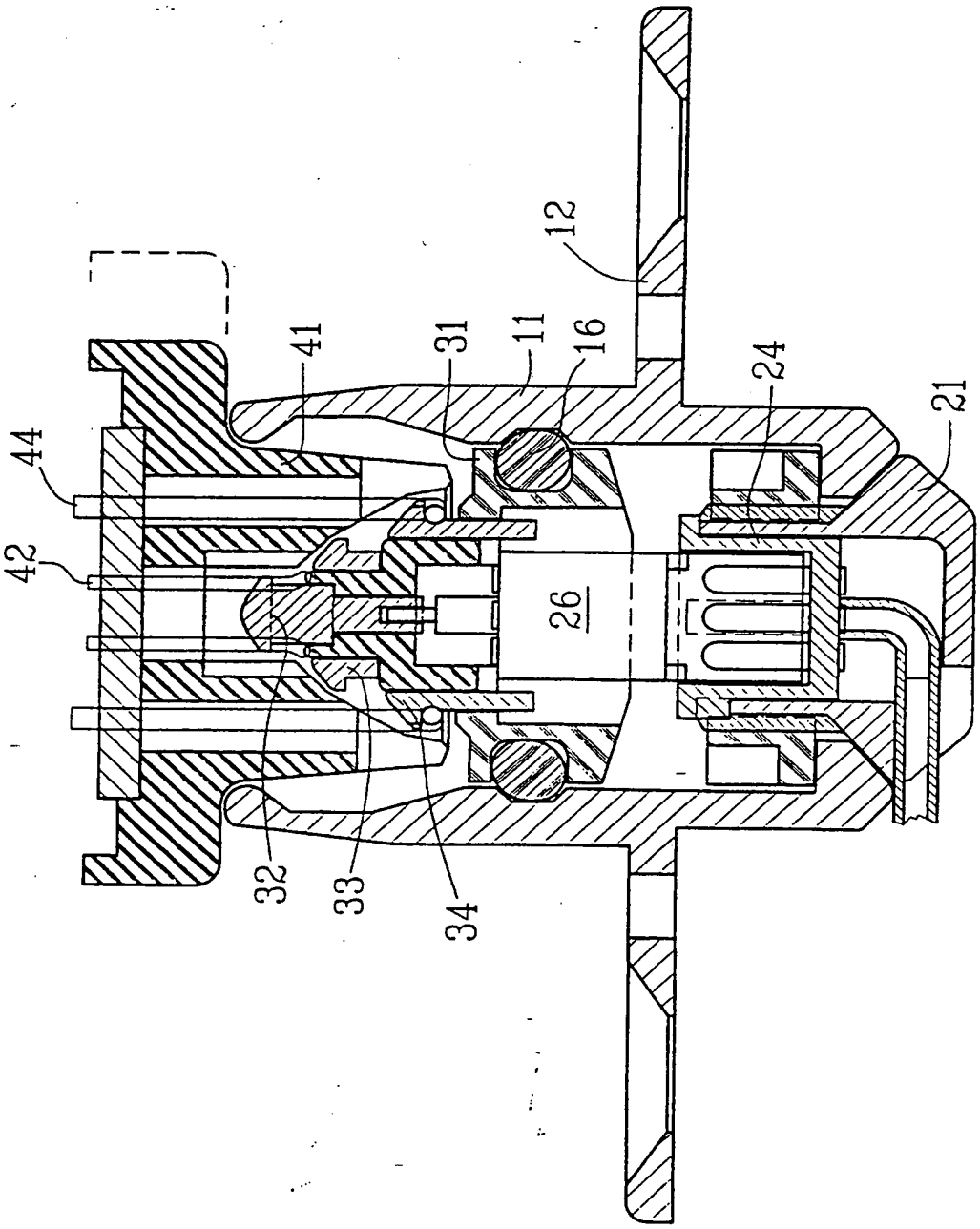


FIG.7

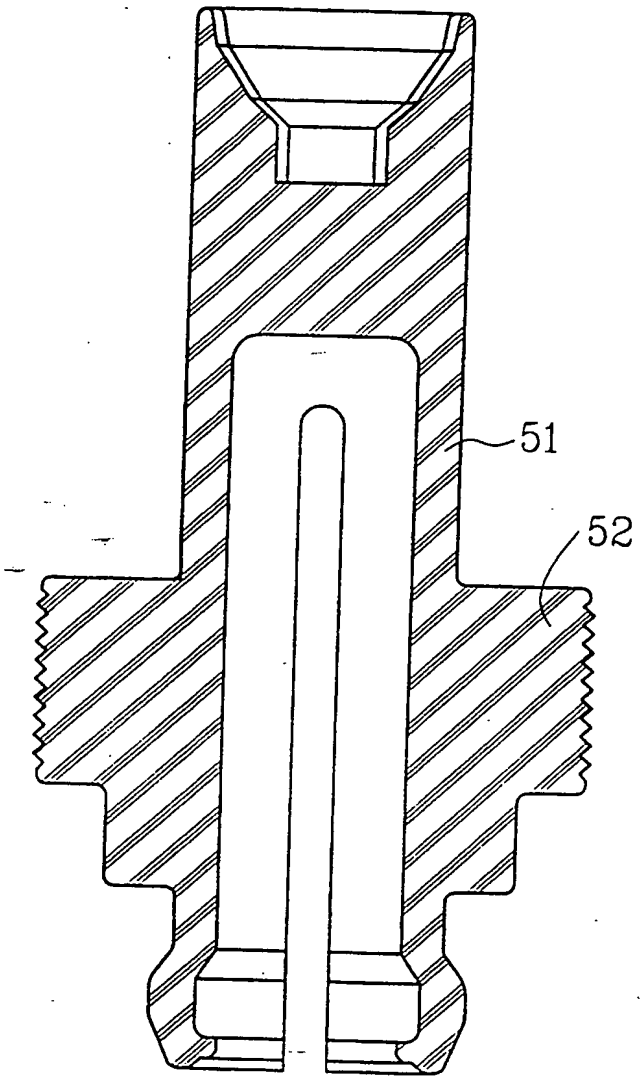


FIG.8

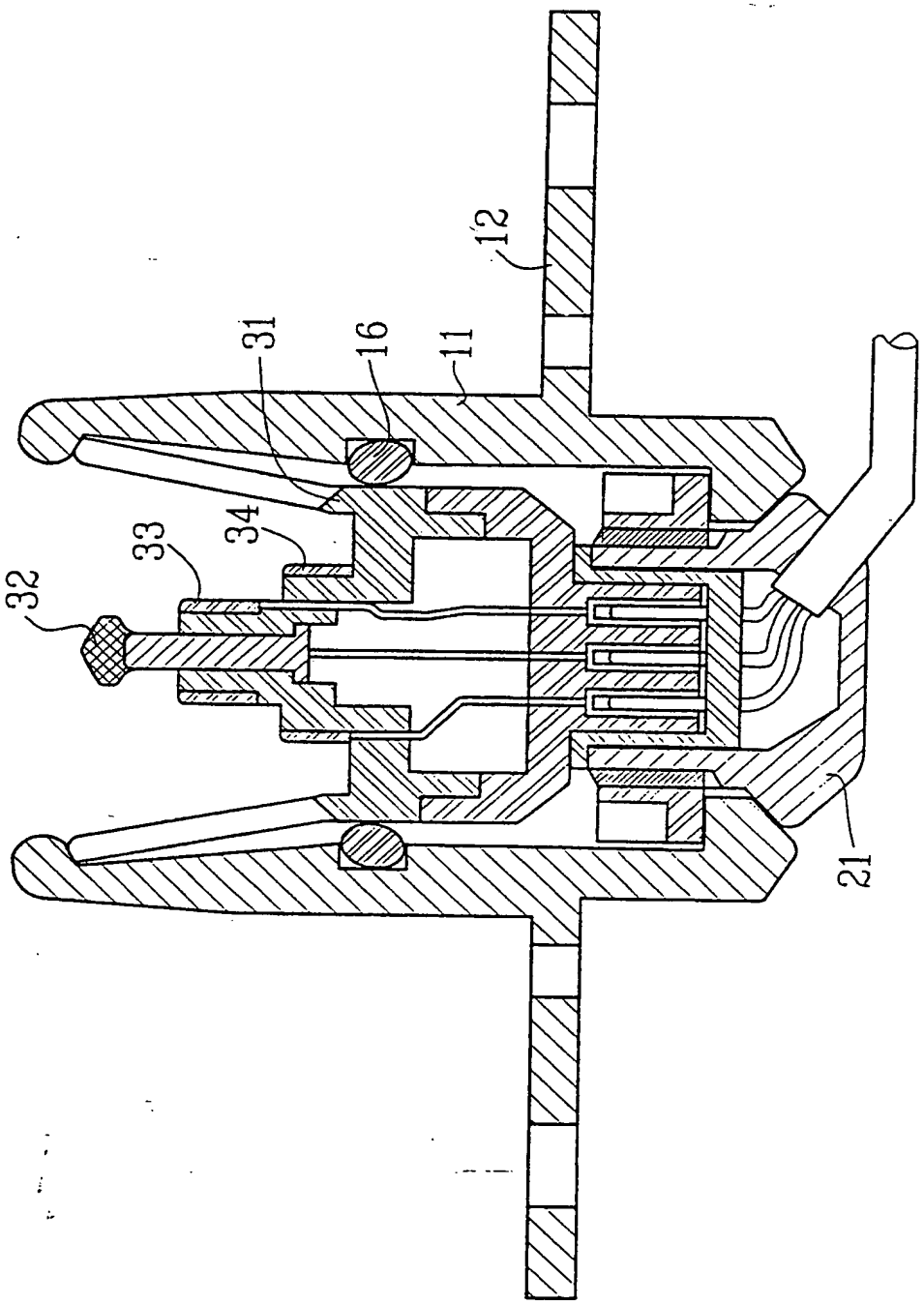


FIG.9

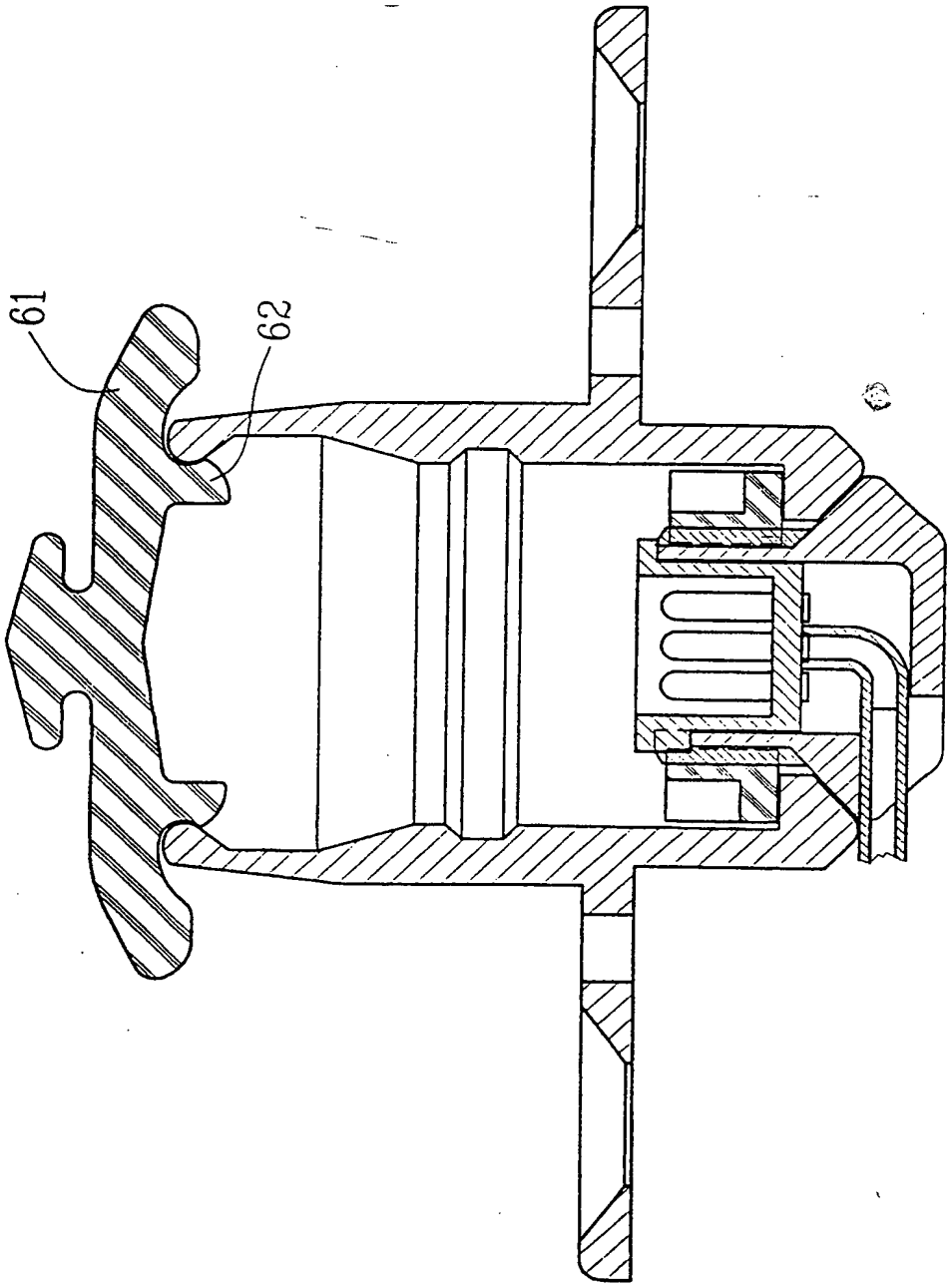


FIG.10

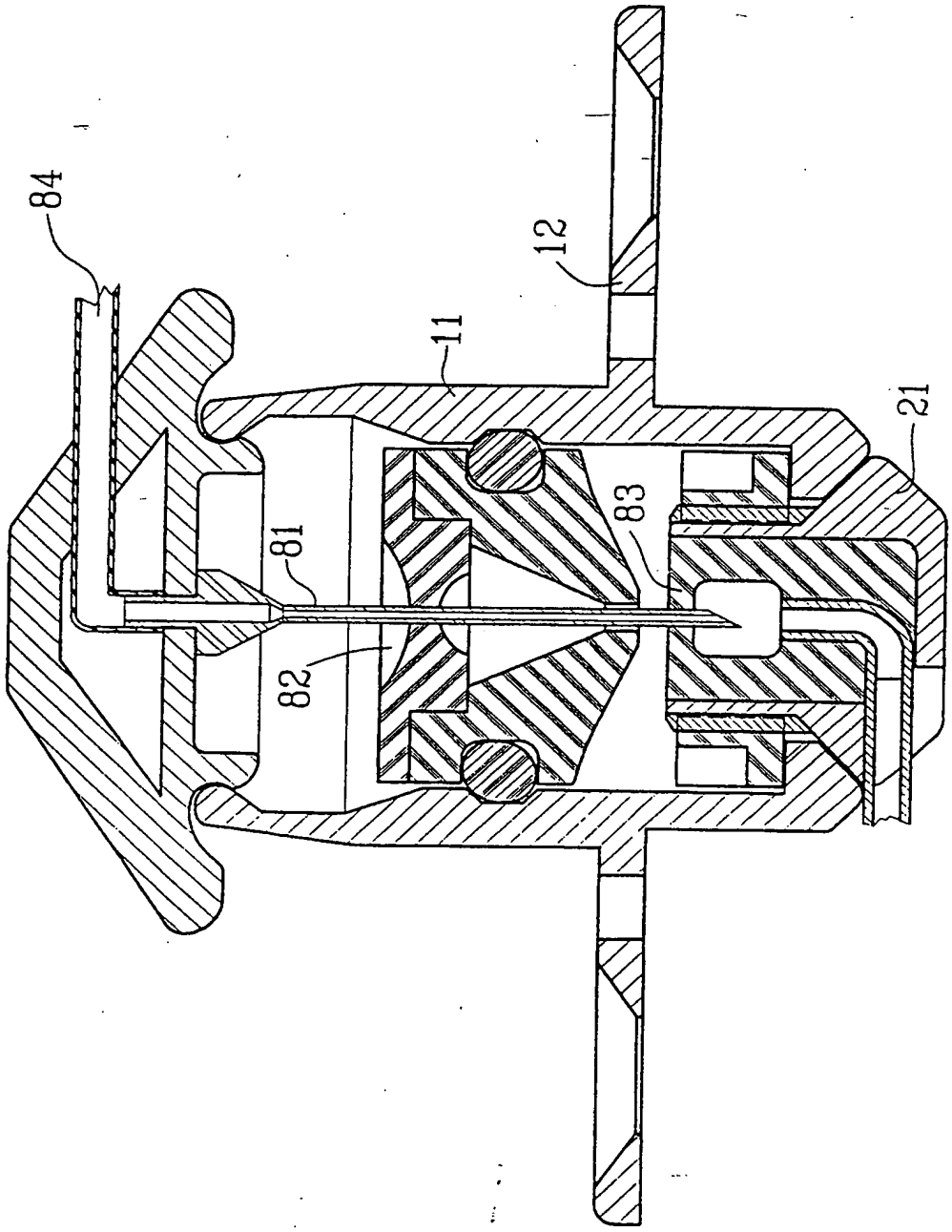


FIG.11

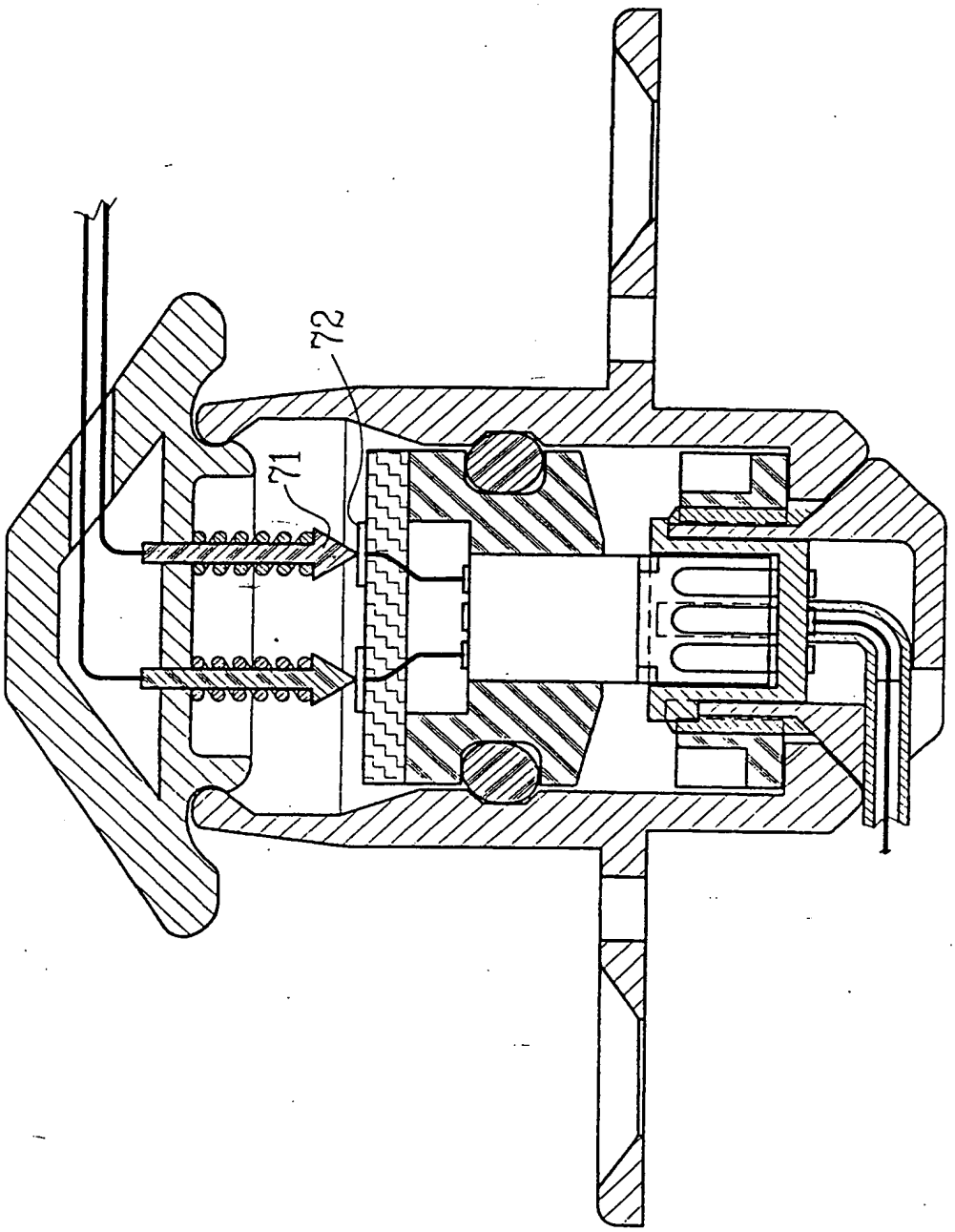


FIG.12

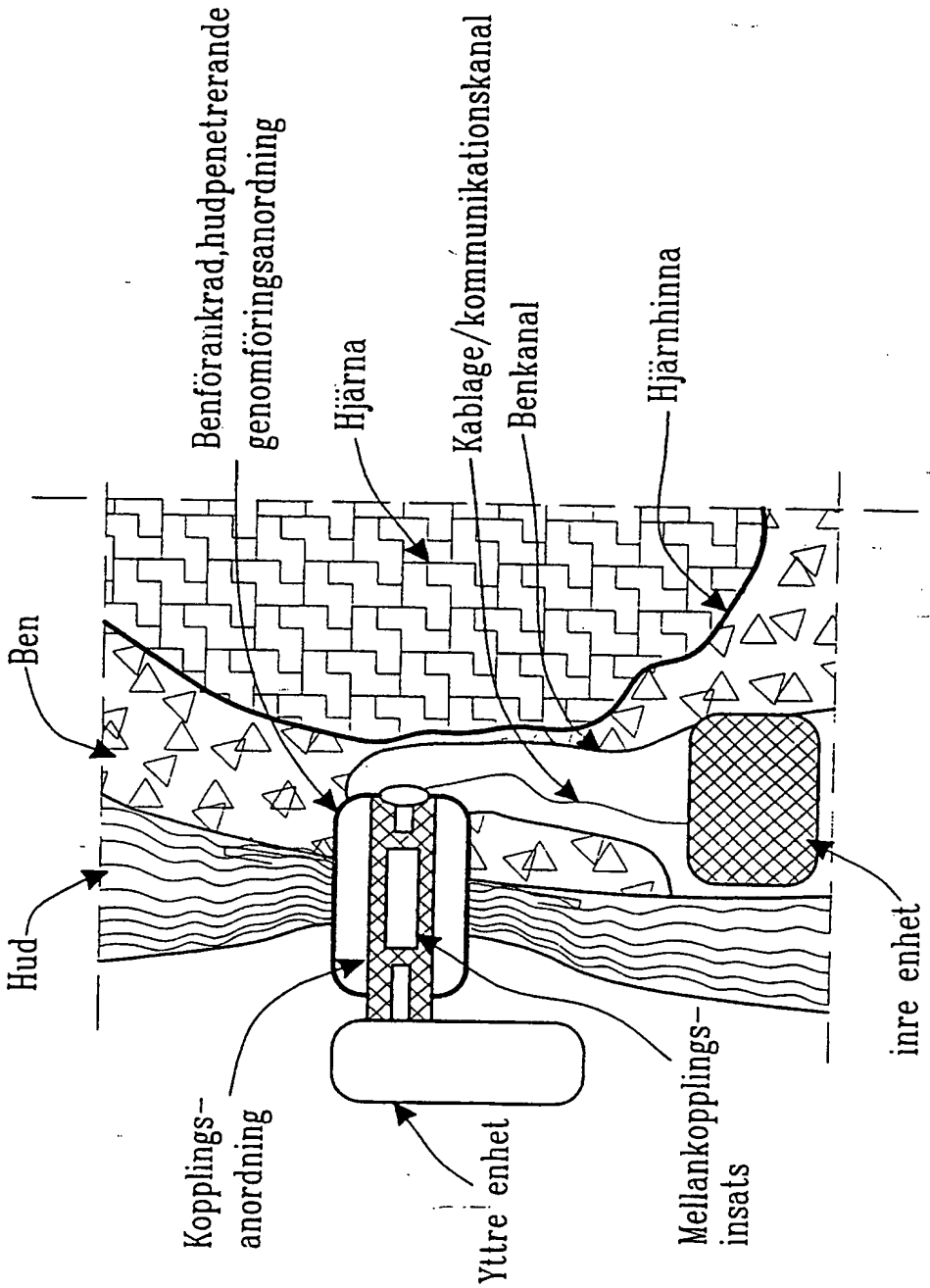
Benförankrad,hudpenetrerande genomföringsanordning
Hjärna
Kablage/kommunikationskanal
Benkanal
Hjärnhinna
Ben
Hud
Kopplings-anordning
Yttre enhet
Mellankopplings-insats
inre enhet

FIG. 13

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/02367

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/28, H04R 25/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61F, H04R

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 4328813 A (RAY), 11 May 1982 (11.05.82), column 3, line 52 - column 4, line 2, figure 4 -- | 1,8 |
| X | US 5507303 A (KUZMA), 16 April 1996 (16.04.96), column 2, line 30 - column 3, line 46, figure 3 -- | 1,8-10,12 |
| X | US 5562670 A (BRÅNEMARK), 8 October 1996 (08.10.96), column 4, line 39 - column 5, line 10, figure 4 -- | 1,8-10 |
| A | WO 9713477 A1 (NOBEL BIOCARE AB), 17 April 1997 (17.04.97) -- | 1,3,5-6,8 |

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 June 1999 | 16 -06- 1999 |
| Name and mailing address of the ISA<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM<br>Facsimile No. +46 8 666 02 86 | Authorized officer<br>Leif Brander<br>Telephone No. +46 8 782 25 00 |

Form PCT ISA 210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/02367

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 4025964 A (OWENS), 31 May 1977 (31.05.77), figure 1, abstract<br>--<br>US 4629451 A (WINTERS ET AL), 16 December 1986 (16.12.86), figure 1, abstract<br>--<br>-------- | 1,3-6,8-10, 12<br><br>1-2,8,11 |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

03/05/99

International application No.
PCT/SE 98/02367

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 4328813 A | 11/05/82 | DE 3141459 A,C | 16/06/82 |
| | | FR 2492251 A,B | 23/04/82 |
| US 5507303 A | 16/04/96 | AU 657332 B | 09/03/95 |
| | | EP 0587649 A | 23/03/94 |
| | | JP 6508534 T | 29/09/94 |
| | | WO 9222107 A | 10/12/92 |
| US 5562670 A | 08/10/96 | AU 681378 B | 28/08/97 |
| | | AU 6073094 A | 03/11/94 |
| | | CA 2122230 A | 28/10/94 |
| | | EP 0622057 A | 02/11/94 |
| | | JP 7000432 A | 06/01/95 |
| WO 9713477 A1 | 17/04/97 | EP 0854694 A | 29/07/98 |
| | | SE 507336 C | 18/05/98 |
| | | SE 9503555 A | 13/04/97 |
| US 4025964 A | 31/05/77 | NONE | |
| US 4629451 A | 16/12/86 | NONE | |

PATENT COOPERATION TREATY

09/581058

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

2000 -04- 11

Göteborgs Patentbyrå Dahls AB

To:

Göteborgs Patentbyrå Dahls AB
Sjöporten 4
417 64 GÖTEBORG

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

| | |
|---|---|
| | Date of mailing *(day/month/year)* 07-04-2000 |
| Applicant's or agent's file reference P15413PC | IMPORTANT NOTIFICATION |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/SE98/02367 | 17-12-1998 | 18-12-1997 |

Applicant
OSSEOFON AB
et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in som Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary axamination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

| | |
|---|---|
| Name and mailing address of the IPEA/<br>Patent- och registreringsverket<br>Box 5055<br>S-102 42 STOCKHOLM<br>Facsimile No. 08-667 72 88<br>Telex 17978 PATOREG-S | Authorized officer<br>Pia Davenas<br>Telephone No. 08-782 25 00 |

Form PCT/IPEA/416 (July 1992)

09/581058

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference P15413PC/SC | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No. PCT/SE98/02367 | International filing date *(day/month/year)* 17.12.1998 | Priority date *(day/month/year)* 18.12.1997 |
| International Patent Classification (IPC) or national classification and IPC7 A 61 F 2/28, H 04 R 25/02 | | |
| Applicant OSSEOFON AB et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 29.06.1999 | 05.04.2000 |
| Name and mailing address of the IPEA/SE<br>Patent- och registreringsverket<br>Box 5055<br>S-102 42 STOCKHOLM<br>Telex 17978 PATOREG-S<br>Facsimile No. 08-667 72 88 | Authorized officer<br>Leif Brander/Els<br>Telephone No. 08-782 25 00 |

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE98/02367

## I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☐ the international application as originally filed.

☒ the description, pages 1-11, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. 1-12, filed with the letter of 03.01.2000,
Nos. _____, filed with the letter of _____.

☒ the drawings, ~~sheets~~/fig 1-13, as originally filed,
~~sheets~~/fig _____, filed with the demand
~~sheets~~/fig _____, filed with the letter of _____,
~~sheets~~/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, ~~sheets~~/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE98/02367

**V. Resoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-12 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | 1-12 | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | 1-12 | YES |
| | Claims | | NO |

2. Citations and explanations

The invention relates to a releasable connection means for a set of cables intended to be connected to a transferring device arranged to a body bone. The invention is intended to provide easy assembly/disassembly and protection of the connection means against overload.

Amended claims 1-12 were filed on 03.01.2000.

The solution according to claim 1 is that the releasably arranged connection means, which is intended to placed below the outer bone surface, comprises a substantially cylindrical unit having tightening surfaces in relation to said transferring device and a connecting surface for fixation to said transferring device.

In claim 2 additional features of the device are disclosed.

Claims 3-8 relates to a transferring device to be used in a connection means according to claims 1-2 and claims 9-12 are directed to middle connection means for introduction into a transferring device according to claims 3-8.

The cited documents, US 4328813 A, US 5507303 A and US 5562670 A, show releasably arranged connection means comprising cylindrical units with tightening surfaces and connection surfaces for fixation to transferring devices but do not disclose connecting means intended to be placed below the bone surface.

.../...

**Supplemental Box**
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

Consequently, the invention according to claims 1-12 is considered novel and not obvious to a person skilled in the art.

The invention is considered to be industrially applicable.

# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

## PCT

To:
GÖTEBORGS PATENTBYRÅ DAHLS AB
Sjöporten 4
S-417 64 Göteborg
SUÈDE



## NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

| | |
|---|---|
| **Date of mailing** (day/month/year)<br>15 July 1999 (15.07.99) | |
| **Applicant's or agent's file reference**<br>P15413PC | **IMPORTANT NOTICE** |

| **International application No.** | **International filing date** (day/month/year) | **Priority date** (day/month/year) |
|---|---|---|
| PCT/SE98/02367 | 17 December 1998 (17.12.98) | 18 December 1997 (18.12.97) |

**Applicant**
OSSEOFON AB et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   EP,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   None

   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   15 July 1999 (15.07.99) under No. WO 99/34754

### REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, **a demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

### REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

**The International Bureau of WIPO**
**34, chemin des Colombettes**
**1211 Geneva 20, Switzerland**

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

Continuation of Form PCT/IB/308

# NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

| Date of mailing (day/month/year) | IMPORTANT NOTICE |
|---|---|
| 15 July 1999 (15.07.99) | |
| **Applicant's or agent's file reference** | **International application No.** |
| P15413PC | PCT/SE98/02367 |

The applicant is hereby notified that, at the time of establishment of this Notice, the time limit under Rule 46.1 for making amendments under Article 19 has not yet expired and the International Bureau had received neither such amendments nor a declaration that the applicant does not wish to make amendments.

SENT BY FAX

09/581058 Date: 981217

# PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* P15413PC

**Box No. I TITLE OF INVENTION** PERCUTANEOUS BONE ANCHORED FEED THROUGH DEVICE

**Box No. II APPLICANT**

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant s State* (i.e. country) of residence if no State of residence is indicated below.)

OSSEOFON AB
Splintvedgatan 7
S-416 80 Göteborg
Sweden

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(i.e country)* of nationality: Sweden

State *(i.e. country)* of residence: Sweden

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

**Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)**

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant s State* (i.e. country) of residence if no State of residence is indicated below.)

HÅKANSSON, BO
Splintvedsgatan 7
S-416 80 Göteborg
Sweden

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e country)* of nationality: Sweden

State *(i.e. country)* of residence: Sweden

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

**Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GÖTEBORGS PATENTBYRÅ AB
Sjöporten 4
S-417 64 Göteborg
Sweden

Telephone No.

Facsimile No.

Teleprinter No.

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

**Box No. V DESIGNATION OF STATES**

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes: at least one must be marked):*

**Regional Patent**

☐ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia **KE** Kenya, **LS** Lesotho, **MW** Malawi, **SD** Sudan, **SZ** Swaziland, **UG** Uganda,

☐ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☐ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** C¶te d'Ivore, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of PCT *(if other kind of protection or treatment desired, specify on dotted line)* _____

**National Patent** *(if other kind of protection or treatment desired specify on dotted line)*

☐ **AL** Albania
☐ **AM** Armenia
☐ **AT** Austria
☐ **AU** Australia
☐ **AZ** Azerbaijan
☐ **BA** Bosnia and Herzegovina
☐ **BB** Barbados
☐ **BG** Bulgaria
☐ **BR** Brazil
☐ **BY** Belarus
☐ **CA** Canada
☐ **CH and LI** Switzerland and Liechtenstein
☐ **CN** China
☐ **CU** Cuba
☐ **CZ** Czech Republic
☐ **DE** Germany
☐ **DK** Denmark
☐ **EE** Estonia
☐ **ES** Spain
☐ **FI** Finland
☐ **GB** United Kingdom
☐ **GE** Georgia
☐ **GH** Ghana
☐ **GM** Gambia
☐ **GW** Guinea-Bissau
☐ **HR** Croatia
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**Box No. VI PRIORITY CLAIM** ☐ Further priority claims are indicated in the Supplemental Box.

| Filing date of earlier application (day/month/year) | Number of earlier application | Where earlier application is: national application: country | regional application:* regional office | international application: receiving Office |
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**Box No. VII INTERNATIONAL SEARCHING AUTHORITY**

**Choice of International Searching Authority (ISA)** *(If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):*

ISA /

**Request to use results of earlier search; reference to that search** *(if an earlier search has been carried out by or requested from the International Searching Authority):*

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**Box No. VIII CHECK LIST; LANGUAGE OF FILING**

This international application contains the following **number of sheets:**

| | | |
|---|---|---|
| request | | 3 |
| description (excluding sequence listing part) | : | 11 |
| claims | : | 2 |
| abstract | : | 1 |
| drawings | : | 13 |
| sequence listing part of description | : | |
| **Total number of sheets** | : | 30 |

This international application is **accompanied by** the item(s) marked below:

1. ☒ fee calculation sheet
2. ☐ separate signed power of attorney
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7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify):*

**Figure of the drawings** which should accompany the abstract: Fig. 1

**Language of filing** of the international application: Swedish

**Box No. IX SIGNATURE OF APPLICANT OR AGENT**

*Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).*

Göteborg 1998-12-17

Ulf Inger
GÖTEBORGS PATENTBYRÅ AB

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18 -12- 1998 Date: 981217

# PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

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International Application No. PCT/SE 98/02367

International Filing Date 17 -12- 1998

The Swedish Patent Office
PCT International Application

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* P15413PC

**Box No. I TITLE OF INVENTION** PERCUTANEOUS BONE ANCHORED FEED THROUGH DEVICE

**Box No. II APPLICANT**

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant s State* (i.e. country) of residence if no State of residence is indicated below.)

OSSEOFON AB
Splintvedgatan 7
S-416 80 Göteborg
Sweden

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(i.e country)* of nationality: Sweden

State *(i.e. country)* of residence: Sweden

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

**Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)**

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant s State* (i.e. country) of residence if no State of residence is indicated below.)

HÅKANSSON, BO
Splintvedsgatan 7
S-416 80 Göteborg
Sweden

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e country)* of nationality: Sweden

State *(i.e. country)* of residence: Sweden

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

**Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**

The person identified below ~~is hereby~~/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GÖTEBORGS PATENTBYRÅ AB
Sjöporten 4
S-417 64 Göteborg
Sweden

Telephone No.

Facsimile No.

Teleprinter No.

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.



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*See Notes to the request form*

**Box No. V DESIGNATION OF STATES**

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes: at least one must be marked):*

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☐ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia **KE** Kenya, **LS** Lesotho, **MW** Malawi, **SD** Sudan, **SZ** Swaziland, **UG** Uganda,

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☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

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| item (1) 18 December 1997 (18.12.97) | 9704752-6 | SE | | |
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**Request to use results of earlier search; reference to that search** *(if an earlier search has been carried out by or requested from the International Searching Authority):*

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**Box No. VIII CHECK LIST; LANGUAGE OF FILING**

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7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
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**Figure of the drawings** which should accompany the abstract: Fig. 1

**Language of filing** of the international application: Swedish

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Göteborg 1998-12-17

Ulf Inger

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# TITEL
# PERCUTAN BENFÖRANKRAD GENOMFÖRINGSANORDNING

## BESKRIVNING

Tekniskt område

Det föreligger ett stort behov vid flera medicinsk tekniska applikationer att överföra elektrisk information och/eller elektrisk energi från en yttre enhet till en inre subcutant permanent implanterad enhet. Dessutom föreligger ett behov av annan långtidsstabil direkt kommunikation från utsidan av kroppen till dess insida exempelvis för att distribuera läkemedel eller åstadkomma luftning av invärtes hålrum t.ex. cellsystemet i processus mastoideus.

Föreliggande uppfinning avser en percutan benförankrad genomföringsanordning företrädesvis medelst vilken en yttre enhet elektriskt kan anslutas till en inre implanterad subcutan enhet.

Varianter av sådana kopplingsanordningar är inte okända men föreliggande uppfinning skiljer sig bl.a. genom att den benförankrade och hudpenetrerande genomföringsanordningen enkelt kan anslutas, under benets yttre begränsningsyta, till/från det implanterade kablaget/anslutningsdonet som förmedlar elektrisk information och/eller energi, läkemedel etc till den inre implanterade enheten. Dessutom är den nya genomföringsanordningen så utformad att dimensionerna är små och att de biokompatibla egenskaperna blir goda.

Den i beskrivningen beskrivna primära tillämpningen är en elektrisk kopplingsanordning, som är utformad för dagligdags användning bl.a. genom att inkopplingen blir enkel och så att väsentligen fri rotationspositionering tillåts samt att kopplingen är lätt att underhålla och att förslitningsdetaljer enkelt kan bytas ut. Kopplingen är dessutom så utformad att den löser ut vid tillräckligt stor yttre mekanisk påverkan.

Uppfinningens bakgrund och teknikens ståndpunkt

Trots ett ökande behov av en percutan kopplingsanordning för stadigvarande bruk speciellt för överförande av elektrisk information och/eller elektrisk energi, finns ingen kommersiellt tillgänglig enhet som är godkänd för kliniskt bruk (till uppfinnarens kännedom December 1997). Detta trots att det finns flera patent inom området. Sammanfattningsvis kan sägas att orsaken till att dessa patent ej ännu lett fram till en kommersiell produkt sannolikt beror på

att patenten beskriver kopplingsanordningar som antingen är för komplicerade i det att de har många poler och ingående komponenter eller att de ej tar hänsyn till alla de mångfacetterade krav ur biokompatibilitets-, anatomisk-, operationsteknisk-, elektrisk-, patientsäkerhetsmässig- och handhavandemässig synvinkel som ställs på en permanent percutan elektrisk kopplingsanordning för dagligdags bruk. I det följande kommenteras några relevanta offentliggjorda patent avseende elektriska kopplingsanordningar speciellt med hänsyn till skillnader med den i föreliggande uppfinning beskrivna kopplingsanordningen.

I US patent 5,562,670 av Brånemark beskrivs en elektrisk kopplingsanordning som appliceras medelst ett gängförsett hylsformat implantat där dess inåt vändande ände har en central urborrning. Kontaktorgan och kablage förs in och fixeras från implantatets utsida. Detta är ett patent av pionjären och upphovsmannen till den idag världsomfattande industriella verksamheten kring titanimplantat avseende dental rehabilitering, benförankrade hörapparater och ansiktsproteser, knä och fingerleder mm, professor P-I Brånemark. Utan hans grundläggande forskningsinsatser kring biomaterialforskning i allmänhet och titanimplantat i synnerhet hade en lång rad av nya tillämpningar/uppfinningar ej kunnat se dagens ljus. När det gäller en praktisk realisering av den elektriska kopplingsanordning som beskrivs i US patent 5,562,670 finns en svaghet i det att det implanterade kablaget och den inre implanterade enheten måste vara så liten att den kan passera genom implantatets centrala urborrning. I de flesta applikationer är dock den inre implanterade enheten för stor för att kunna passera in genom implantatets centrala urborrning. I dessa fall måste enheterna sannolikt inopereras som en integrerad enhet eller monteras ihop med själva implantatet på plats eller anslutas medelst ytterligare en implanterad och tillräckligt liten kopplingsanordning. Skall kontaktdonet repareras eller underhållas, vilket är nödvändigt med tanke på den miljö som ett hudnära implantat utsätts för (kontaktytor oxideras etc), måste detta ske i själva hylsan på patienten. Önskar man ta bort/byta ut genomföringsanordningen måste även hela det implanterade kablaget tas bort. Fixering av implantatet med gänga innebär att den benförankrade delen av implantatet måste ha tillräckligt stor diameter för att rymma även gängan vilket klart begränsar möjligheterna att även rymma kopplingsdetaljer inom densamma. Att rymma kopplingsdetaljer i den benförankrade delen av genomföringsanordningen är önskvärt för att det reducera genomföringsanordningens totala höjd. Ett väl fungerande genomföringsorgan bör inte sticka ut utanför hudnivån med mer än 1-3 mm för att undvika skador från eventuellt yttre mekaniskt våld och för att implantatet skall upplevas som acceptabelt ur estetiskt synvinkel. Ett skruvimplantat måste dessutom roteras vid appliceringen vilket innebär att ett

asymmetriskt utförande av implantatet, är mycket svårt att realisera. Ett asymmetriskt utförande av implantatet är önskvärt eftersom bentjockleken, där implantatet av praktiska skäl måste placeras, är i regel så tunt att kablaget måste lämna implantatet i radiell riktning. Dessutom måste den inre implanterade enheten, om den förmonterats och passerar genom genomföringsanordningen (p.g.a. den är för stor att applicera efteråt genom urborrningen), rotera med vid appliceringen, vilket även detta medför praktiska problem.

I US patent 3,870,832 av Fredricson visas en kopplingsanordning för applicering av en mikrofon som i princip överensstämmer med Brånemarks patent. Fredricson visar att retentionen av mikrofonelementet görs med en låsmutter som appliceras med utvändig gänga på implantatet, vilket torde innebära potentiell risk för bakterieansamling och risk för hudirritation. För övrigt kännetecknas konstruktionen enligt detta patent av samma svagheter beskrivits ovan avseende patent nr. 5,562,670.

I US patent 5,604,976 av Stobie et al. beskrivs en kopplingsanordning för ett stort antal ledare vars inre kopplingsdel ej är avsedd att sänkas ned under benets yttre begränsningsyta utan fixeras ovanpå densamma. I denna kopplingsanordning leds kablaget till den inre implanterade enheten ovanpå benet men under mjukvävnaden. Problem som rapporterats vid kliniska försök med dylikt arrangemang visar att ett kablage av realistisk dimension (minimum 1-2 mm i diameter) och som är svagt elastiskt, skapar biokompatibilitetsproblem vid hudgenomgången, sannolikt föranlett av att relativa rörelser mellan hud och ben kan ske med ett främmande material emellan. Dessutom kan den nödvändiga hudreduktionen äventyras om inte kablaget har en mycket liten diameter. Kopplingen är isärtagbar med hjälp av ett verktyg för att skruva loss ett skruvförband och kan rimligen ej kopplas isär i dagligdags bruk. Denna förbindningsteknik innebär också att rotation av den yttre kopplingsdelen ej är möjlig samt att ett överbelastningsskydd vid yttre påverkan saknas.

I US patent 5,507,303 av Kuzma visas en kopplingsanordning där implantatet visserligen är förankrat till skallbenet men där huden/benhinnan närmast implantatet är avskild från skallbenet med en stor fläns. Lång erfarenhet av hudpenetrerande titanimplantat i skallbenet visar att det är av yttersta vikt att huden runt penetrationsområdet har genomgått adekvat hudreduktion och att den förtunnade huden tillåts växa fast mot benhinna och skallben (Tjellström, Anders et al, The Bone Anchored Hearing Aid - design principles, indications, and longterm clinical results, Otolaryngologic Clinics of North America, vol 28(1), 1995, pp

53-72). Flänsen i den aktuella kopplingen hindrar att huden växer fast mot benet/benhinnan och hudkomplikationsfrekvensen kan väntas bli relativt hög. Dessutom är hela kopplingsanordningen placerad utanför både benet och huden vilket innebär att dess utskjutande del ovanför hudytan blir betydande. Retentionen mellan kopplingsdelarna sker med magnetkraft.

I US patent 4,025,964 av Owens beskrivs en kopplingsanordning som till skillnad från kopplingsanordningarna ovan ej är stabilt förankrad till benet. Även små rörelser av implantatet relativt hud kommer att innebära stor risk för hudirritation. Fixering mellan kopplingens hon- och handel sker med magnetisk attraktionskraft och delarna kan ej inbördes roteras.

Även US patent 3,995,644 av Parsons beskriver en kopplingsanordning som enbart är fixerad till huden avsedd att överföra en elektrisk signal företrädesvis för elektrisk stimulering av muskelenheter. På grund av att även små relativa rörelser mellan hud och implantat skapar irritation, torde denna typ av kopplingar enbart komma ifråga för temporärt och tidsbegränsat bruk.

Slutligen finns ett antal kopplingsanordningar som är avsedda att användas helt subcutant, såsom US patent 4,495,917 av Byers, men dessa är så olika föreliggande uppfinning vad gäller funktionskrav och konstruktionslösningar att ytterligare analys ej synes meningsfull.

US-A-4,328,813 avser ett system för förankring av en hjärnkabel, och är enbart avsett att geometriskt fixera eller låsa en kabel, såsom en elektrod för stimulering av en viss punkt i hjärnan. Kabeln är därvid avsedd att ledas under skalpen till en elektrisk stimulator. Då implantatet är utfört i ett elastiskt material och slitsförsett, kan implantatet inte användas för benförankrad percutan genomföringsanordning.

SE-C-503,790 avser ett passivt skruvimplantat för överförande av vibrationer från en yttre vibrator (högtalare) till skallbenet. Ett sådant implantat kan inte överföra elektriska signaler, energi eller läkemedel till kroppens inre och har vid sin konstruktion inte konfronterats med de problemställningar som föreliggande uppfinning ger en lösning på.

<u>Ändamålet med föreliggande uppfinning och principiella egenskaper</u>

Som tidigare nämnts finns ett stort behov i flera medicinskt-tekniska applikationer att överföra elektrisk information och/eller elektrisk energi eller på annat sätt kommunicera (exem-

pelvis för att distribuera läkemedel och åstadkomma luftning av invärtes hålrum och cellsystem) från en yttre enhet till en subcutan implanterad inre enhet. Sådana subcutana implanterade enheter kan vara hörseltekniska hjälpmedel exempelvis kokleära implantat, mellanöreimplantat, benledningsimplantat, anordning för tinnitussuppression och andra medicintekniska hjälpmedel t.ex. stimulatorer av olika slag, registrering av biologiska signaler, pumpar för distribution av läkemedel, evakuering av vätska etc. I princip består en sådana anordningar av följande väsentliga delar: yttre enhet, kopplingsanordning, hudpenetrerande och benförankrat genomföringsorgan, kablage /kommunikations kanal och subcutan implanterad inre enhet. En principiell anordning utnyttjande en kopplingsanordning enligt föreliggande uppfinning är presenterad i Figur 13, där den yttre enheten exempelvis kan vara en hörapparat utan högtalare och den inre enheten en vibrator för generering av benledningsljud. Anledningen till att ett kablage/kommunikationskanal mellan genomföringsanordningen och den inre enheten behövs är att bentjockleken, där genomföringsanordningen av praktiska och anatomiska skäl måste placeras, är så tunn att den inre enheten ej får plats. Å andra sidan finns det gott om plats ett stycke därifrån och närmre hörselgången i det område av temporalbenet som kallas processus mastoideus. Var och hur den inre enheten placeras är därvid avhängigt tillämpningen.

Även om föreliggande uppfinning avseende genomföringsanordningen kan användas för annan långtidsstabil kommunikation beskrivs i det följande den primära applikationen där en yttre enhet elektriskt kan kopplas till en inre implanterad subcutan enhet medelst föreliggande föreslagna genomföringsanordning. Varianter av sådana kopplingsanordningar är inte okända men föreliggande uppfinning är unik i följande avseenden:

1. angöringen/fixeringen mellan den benförankrade delen och den hudpenetrerande genomföringsanordningen och kablaget sker under yttre bennivån, företrädesvis i genomföringsanordningens bottendel.

Fördelarna med denna lösning är

a. att kablaget och den implanterade inre enheten kan monteras respektive demonteras separat vilket inte bara är väsentligt för att underlätta vid första installationen utan i synnerhet vid framtida händelser av typen hudirritation/skador/service/uppdateringar då den benförankrade och hudpenetrerande genomföringsanordningen respektive kablaget (eventuellt inklusive inre enhet) behöver bytas ut oftast oberoende av varandra. Vidare kan genom-

föringsanordningen tagas bort så att intakt hud kan återställas utan att kablage och en inre implanterad enhet påverkas. På detta sätt kan alla inre vitala delar behållas vilande under hud samtidigt som huden över penetrationsområdet återställs för längre eller kortare tid. Detta förfarande kan vara av stor betydelse om patienten vill upphöra med behandlingen för en tid men ha kvar möjligheten att lätt återuppta behandlingen när behovet eventuellt återuppstår;

b. att genomföringsanordningen och kablaget (inklusive i andra ändan anslutna inre enheter) kan roteras oberoende av varandra vid monteringen respektive vid en eventuell demontering;

c. att huden närmast penetrationsområdet kan reduceras till önskad tjocklek och tillåtas att vila/läka fast mot benvävnad och benhinna vilket möjliggörs genom att kablaget dras under och inte över den yttre benytan.

2. Genomföringsanordningen som är försänkt i benvävnaden förankras medelst radiella armar placerade utanför benets ytteryta och som i sin tur skruvas fast i benvävnaden.

Fördelarna med denna lösning är:
att en första kontaktanordning kan placeras inuti benförankringsdelen av genomföringsanordningen (under den yttre benytan) utan att dess ytterdiameter blir oönskat stor. Detta är möjligt eftersom benförankringsdelen av genomföringsanordningen ej innehåller gängor vilka annars tar stor plats. Genom att placera en del av kopplingsanordningen i benförankringsdelen av genomföringsanordningen kan den genom huden utstickande delen av genomföringsanordningen vara minimal, vilket är en fördel dels ur estetisk synpunkt samt dels med hänsyn till risken för yttre mekanisk skada av implantatet;

3. Kopplingsanordningen innehåller en mellankopplingsenhet, placerad i genomföringsanordningens yttre del. Härvid uppstår två kopplingsanordningar, en yttre för anslutning mot yttre enheten och en inre för anslutning mot kablaget.

Denna lösning erbjuder följande fördelar:

a. mellankopplingsenheten som exponeras mot den yttre miljön är en förslitningsdetalj utformad så att den är enkel att byta om dålig kontakt på grund av oxidskikt etc uppstår eller om den skadas på annat sätt;

b. mellankopplingsenheten i kombination av en tätningsring skyddar den inre och känsligare kopplingsanordningen från yttre miljöpåverkan. Dessutom tjänar mellankopplingsenheten i kombination tätningsringen som en första biologisk spärr mot passage av oönskade substanser/bakterier till vävnaden innanför genomföringsanordningen. Den huvudsakliga spärren i detta avseende är dock skruvförbandet mellan genomföringsanordningen och kablagets anslutningsdon;

c. den yttre kopplingsanordningen kan utformas så att den, tillåter fri rotationspositionering, är enkel att koppla in/ur samt tjänstgör som ett överbelastningsskydd.

Erfarenheter från 20 års utvecklingsarbete med benförankrade hörapparater (Håkansson, Bo et al, The Bone Anchored Hearing Aid, Edited by Dan Tolman & P-I Brånemark, to be published) där över 5000 patienter opererats och försetts med en mekanisk bajonettkoppling (SE-C-8107161-5) visar att alla ovanstående aspekter är betydelsefulla för att en kopplingsanordning skall fungera i kliniskt bruk under lång tid. Det kan tyckas att det ligger en begränsning i att föreliggande uppfinning knappast kan realiseras med fler poler än 4-6, bibehållande rimliga dimensioner. Om större antal poler önskas, som exempelvis hos dagens kokleära implantat där upp till 20-30 elektroder skall försörjas separat, är det lämpligt att utnyttja s.k. multiplexering. Multiplexering innebär att informationen överförs sekventiellt i en signalledning genom den percutana elektriska kopplingen för att sedan på elektronisk väg, delas upp i den inre implanterade enheten och distribueras till önskat antal elektroder. Multiplexering är välkänd teknik då den används inom all kommunikation (tele och TV) där man normalt inte har tillgång till parallella ledningar. Det som dessutom starkt talar emot ett stort antal poler i percutan elektrisk kontakt är att komplexitet och begränsningar av både medicinsk och teknisk karaktär ökar dramatiskt med ökat antal poler. I de flesta tillämpningar klarar man sig generellt med tre poler som då kan vara plus respektive minuspol samt en signalledning. I specifika hörseltillämpningar önskar man ibland att driva en push-pull vibrator där då två ledningar är signalledningar och en ledning är spänningsmatning.

Kort beskrivning av figurer

Figur 1 är en sammanställande tvärsnittsvy av ett hjälpmedel där en elektrisk kopplingsanordning enligt föreliggande uppfinning utnyttjas.

Figur 2 är en tvärsnittsvy av föreliggande uppfinning bestående av den hudpenetrerande och benförankrade genomföringsanordningen med kablage angjort i genomföringsanordningens

bottendel samt med mellankopplingsenhet och tätningsring monterad. I detta utförings-exempel av mellankopplingsenheten angriper kontaktbleck i det yttre kontaktdonet enheten med radiell kraft.

Figur 3 visar en tvärsnittsvy av en genomföringsanordning visad i Figur 2.

Figur 4 visar utföringsformen enligt Fig. 3 sedd från ovan.

Figur 5 visar genomföringsanordningen enligt Fig. 2-4 med ett kopplingsdon för koppling till en inre enhet

Figur 6 visar olika detaljer i en mellaninsats för insättning i genomföringsenheten enligt Fig. 2-4

Figur 7 visar ett utföringsexempel av hur den yttre enheten ansluts till mellankopplings-enheten.

Figur 8 visar ett enkelt verktyg för att montera respektive frigöra mellankopplingsenheten samt hur kontaktytor kan rengöras/underhållas.

Figur 9 visar ett alternativt utförande av mellankopplingsenheten, där mellankopplingsen-heten fixeras med hjälp av slitsade radiellt fjädrande armar.

Figur 10 visar ett lock som används då mellankopplingsenheten och dess kontaktytor bör skyddas exempelvis vid bad i saltvatten och bastu.

Figur 11 visar ett utföringsexempel hur uppfinningen kan användas vid distribution av läkemedel alternativt evakuering / luftning av invärtes hålrum.

Figur 12 visar en alternativ kontaktdonsutformning där kontaktblecken i det yttre kontakt-donet ansluts med axiell kontaktkraft.

Figur 13 visar en principiell bild på ett medicin-tekniskt hjälpmedel där en kopplingsanordning enligt föreliggande uppfinning är på plats.

Beskrivning av utföringsexempel

Med 1 betecknas ett skallben med dess hud och hudvävnad 2, som förtunnats med känd kirurgisk teknik. En elektrisk koppling 3 tillverkad i vävnadsvänligt material såsom titan är förankrad i skallbenet 1 med skruvar 4, lämpligen i samma typ av material, fästade i nämn-da ben, varvid del av kopplingen är placerad i själva benet genom inborrning och försänk-ning i det borrade hålet 5. Ur kopplingens 3 bottendel är ett kablage 6 utdraget till en ej visad inre enhet, såsom en mot hörselbenen verkande vibrator eller annat.

Kopplingen 3 omfattar enl. Fig. 2-4 en genomföringsdel 11, vilken uppvisar ett antal armar 12 försedda med hål 13 för en skruvgenomföring för ankring medelst skruv 4. Antalet armar

kan vara tre, fyra, fem eller flera beroende på storlek och tänkt placering. Armarna 12 är vrid- och böjbara för att medge maximal anpassning till underlaget till vilket de skall skruvas. Genomföringsdelen 11 uppvisar utåt en väsentligen cylindrisk form, undantagandes armarna 12, samt likaså ett väsentligen cylindrisk inre. I den övre delen 14 är genomföringen 11 förtunnad för att medge deformation om stor belastning skulle uppstå på genomföringen 11. På sin insida uppvisar genomföringen 11 i denna utföringsform ett spår 15 för upptagande av en O-ring 16. I genomföringens 11 bottendel 17 är ett hål 18 upptaget, varvid dess utåtvända begränsningsytor 19 är snedställt anordnade. Genomföringsanordningen 11 är lämpligen ruggad i sin nedre cylindriska del, bottendelen 17, för att medge anpassning till den vävnad 1 som den är införd i. Genomföringsdelen 11 är visad som en integral enhet, men kan också vara delad och sammanfogningsbar medelst ett skruvförband över det plan i vilket armarna 12 är anordnade.

I genomföringsdelen 11 är i denna utföringsform ett kopplingsdon 21 infört underifrån och medelst skruvförband medelst en låsmutter 22 fast anordnat till genomföringsanordningen 11. Kopplingsdonet 21 uppvisar en konisk övre begränsningsyta 23 avsedd att väl anligga mot genomföringsanordningens 11 hål 18 och dess begränsningsytor 19. I kopplingsdonet 21 är en elektrisk kopplingsenhet 24 anordnad, vars kablage 6 är utdraget genom kopplingsdonets 21 en sidoöppning 25.

Till kopplingsenheten 24 är en andra kopplingsenhet 26 anordnad, varvid den ena enheten uppvisar hanstift eller -bleck och den andra enheten uppvisar honstift eller -bleck för uppnående av god elektrisk ledning mellan kopplingsenheterna 24 och 26.

Kopplingsenheten 26 är i sin tur införd i en mellaninsats 31 kring vilken tre olika poler 32, 33, 34 är anordnade och kopplade via bleck och ledningstrådar till kopplingsenheten 26, vilken utgöres av en i cylindriska delar uppbyggd enhet i plast eller annat icke-ledande material. I centrum på mellaninsatsen 31 är ett kontaktbleck för pluspol 32 placerad. Från denna pluspol 32 leder en kopplingstråd till en motsvarande pluspol 26p på kopplingsenheten 26. Kring mellaninsatsen övre cylindriska del är ett kontaktbleck för signalpol 33, placerad, vilken via en ej visad genomföring står i anslutning med en motsvarande signalpol 26s i kopplingsenheten 26. Vidare är ett kontaktbleck för minuspol 34 anordnad runt mellaninsatsens 31 nedre cylindriska del, varvid denna minuspol 34 står i ej visad kontakt med motsvarande minuspol 26m i kopplingsenheten 26.

Till mellaninsatsen 31 med dess olika kontaktbleck är en yttre kontakt 41 ansluten, vilken kan utgöras av en hörapparats mikrofonenhet, annan signalbehandlingsenhet eller, som framgår av Fig. 11 en enhet för distribution av läkemedel eller luftning av ett hålrum. Den yttre kontakten 41 omfattar ett antal stift 42, 43, och 44 som ansluter till sitt respektive kontaktbleck 32, 33, och 34. Stiften 42 anligger mot centrumkontaktblecket 32, varvid det i sin spets är bockat utåt från centrum för att vila mot blecket 32. Likaså är bleckets 43 spets bockad utåt för att ansluta till blecket 33. Stiften 44 är bockade inåt mot centrum för att ansluta under kontaktbleckets 34 kant, vilken kant kan vara stegad för att medge stegning-/variering av kontakthusets/hörapparatens läge i rotationsled. Härvid är blecket 34 vikt uppåt på två motstående ställen för att medge att stiften 44 nedföres under kontaktbleckets 34 kant.

Stiften 44 har framförallt också till uppgift att kvarhålla den yttre kontakten 41 till mellaninsatsen 31. Vid en tillräckligt hög belastning går dock stiften över kanten för att skapa en säkerhetsfrigöring av den yttre kontaktdelen visavi den inre mellaninsatsen och därmed hela genomföringsanordningen.

Med 51 betecknas ett verktyg för uttagande och införande av mellaninsatsen med kopplingsenheter ur genomföringsanordningen 11. Verktyget 51 är härvid tubulärt och slitsat så det medelst greppet 52 kan pressas samman för att kvarhålla en mellaninsats 31.

I figur 10 visas ett lock 61, som kan placeras över mellaninsatsen 31 då den yttre kontakten 41 är borttagen. Det är lämpligt att sätta på ett lock 61 vid vistelse i saltvatten och bastu. Locket 61 uppvisar härvid en vulst 62 som snäpper ned över genomföringsanordningens 11 överkant.

I Fig. 9 visas en alternativ fixering av mellankopplingen 31, varvid dess övre del är slitsad och spänner utåt, varvid denna övre del spänner in under genomföringsanordningens 11 övre dels kant, som härvid är vulstformad. Vidare visar utföringsformen en alternativ placering av O-ringen.

I Fig. 12 visas en alternativ kontaktdonsutformning med axiellt fjädrande kontaktstift 71 som anligger mot ett mönsterkort 72 med ledningsbanor.

Fig. 11 visar som nämnts en utföringsform för distribution av läkemedel i form av lösning

varvid en kanyl 81 penetrerar ett i mellaninsatsen anordnat membran 82, liksom ett i kopplingsdonet anordnat membran 83. Till kanylen 81 leder en slang 84, för tillförsel av läkemedelslösning, samt från kopplingsdonets nedre del leder en slang för distribution vid lämpligt säte i kroppen. Dessa slangar och kanyl kan också användas för luftning av en hålighet, såsom ett mellanöra med ständiga inflammationer.

**PATENTKRAV**

1. Kopplingsdon för kablage för transferring av elektrisk information/energi till och/eller ifrån en implanterad enhet eller för administrering av läkemedel eller evakuering eller luftning av invärtes hålrum, vilket kopplingsdon är avsett att anslutas till en genomförings-anordning anordnad till ett kroppsben,
**kännetecknat** av, att
kopplingsdonet (21), som är löstagbart anordnat gentemot nämnda genomföringsanordning omfattar en väsentligen cylindrisk enhet uppvisande mot nämnda genomföringsanordning tätande ytor (19), samt en kopplingsyta för anslutning av fixerande anordning för fixering till nämnda genomföringsanordning (11).

2. Kopplingsdon enligt krav 1, **kännetecknat** av, att
det omfattar en membranförsedd (83) genomföring.

3. Genomföringsanordning för kommunikation till/från en implanterad enhet eller för administrering av läkemedel, omfattande en i ett ben nedsänkbar kroppsdel, samt en överbenytan liggande del, och omfattande en väsentligen cylindrisk kropp (11)
**kännetecknad** av, att
den över benytan liggande delen (11) av genomföringsanordningen (3) uppvisar ett antal radiella armar (12) anordnade att fästas till det ben (1) vari anordningen är införd.

4. Genomföringsanordning enligt krav 3, **kännetecknad** av, att
de radiella armarna (12) är böjbara och vridbara för anpassning till underlaget.

5. Genomföringsanordning enligt krav 3, **kännetecknad** av, att
den cylindriska kroppens (11) uppvisar sådan ytegenskap att den utgör en integral enhet mot vävnaden efter inoperation.

6. Genomföringsanordning enligt krav 3, **kännetecknad** av, att
den i benvävnaden nedsänkta kroppsdelen (17) och den över benytan liggande kroppsdelen (14) utgöres av två individuella delar vilka genom frigörbart förband är anslutna till varandra.

7. Genomföringsanordning enligt krav 3, **kännetecknad** av, att

kroppens (11) övre del (14) uppvisar en försvagad zon.

8. Genomföringsanordning enligt krav 1-2, **kännetecknad** av, att
den i sin bottendel (17) uppvisar ett genomgående hål (18) med mot kopplingsdonet (21) enligt krav 1, tätande kopplingsytor (19).

9. Mellankopplingsdel för införande i en genomföringsanordning enligt krav 3-8, **kännetecknad** av, att den omfattar ett yttre kontaktdon (41) och en inre mellaninsats (31), varvid kontaktdonet (41) är löstagbart lagrat i nämnda mellaninsats.

10. Mellankopplingsdel enligt krav 9, **kännetecknad** av, att
nämnda mellaninsats omfattar ett antal kontaktbleck för åstadkommande av elektrisk genomföring.

11. Mellankopplingsdel enligt krav 9, **kännetecknad** av, att
mellaninsatsen (31) omfattar membranförsedd (82) genomföring.

12. Mellankopplingsdel enligt krav 9, **kännetecknad** av, att
det yttre kontaktdonet (41) och mellaninsatsen (31) är anordnade att frigöras från varandra vid en förutbestämd belastning på det yttre kontaktdonet (41)

**SAMMANDRAG**

Föreliggande uppfinning avser en percutan benförankrad genomföringsanordning för åstadkommande av elektrisk signal och/eller energiöverföring och/eller distribution av läkemedel och/eller ventilering av ett kroppshålrum, varvid anordningen omfattar en genomföringsanordning (3), ett kopplingsdon (21) anslutet till kroppens inre, en mellaninsats (31) med kopplingsenheter (24, 26), samt en yttre kontaktenhet (41) (Fig. 1)